EXHIBIT 1

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
SOUTHERN DIVISION

UNITED STATES OF AMERICA
Ex Rel
VEN-A-CARE OF THE FLORIDA KEYS, INC.
a Florida Corporation,
by and through its principal officers and directors,
ZACHARY T. BENTLEY and
T. MARK JONES,
Plaintiff,

v.

[redacted]

DEY, INC.; [redacted]; EMD PHARMACEUTICALS, INC.; [redacted]

LIPHA, S.A.; [redacted]

MERCK KGaA; MERCK-LIPHA, S.A.; [redacted]

CIVIL ACTION NO.
95-1354-CIV-GOLD

FILED IN CAMERA
AND UNDER SEAL
PURSUANT TO
31 U.S.C. §3730

FOURTH AMENDED
COMPLAINT
For Money Damages and
Civil Penalties Under The
False Claims Act
31U.S.C. §§3729-3732

[redacted]

Defendants.

FOURTH AMENDED COMPLAINT
FOR MONEY DAMAGES AND CIVIL PENALTIES UNDER THE FALSE CLAIMS ACT 31 U.S.C. §§3729-3732

COMES NOW, the UNITED STATES OF AMERICA ("UNITED STATES" or "GOVERNMENT"), by and through VEN-A-CARE OF THE FLORIDA KEYS, INC. ("VEN-A-CARE" or "the Relator"), and its principal officers and directors, ZACHARY T. BENTLEY, and T. MARK JONES, and by and through the undersigned attorneys on behalf of the UNITED STATES and on the Relator's own behalf and bring this action against, [redacted] DEY, INC. [redacted] EMD PHARMACEUTICALS, INC.; [redacted]

[redacted]; LIPHA, S.A.; [redacted]; MERCK KGaA; MERCK-LIPHA, S.A.; [redacted] (sometimes referred to collectively as, "DEFENDANT DRUG MANUFACTURERS" or "DEFENDANTS"), for money damages and civil penalties arising out of the DEFENDANTS' violations of the Federal False Claims Act ("False Claims Act"), 31 U.S.C., §§3729-3732.

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SECTION NO. 1

SUMMARY OF THE ACTION

1. This is an action for damages, treble damages, restitution, civil penalties, pre-judgment interest, equitable relief and for attorneys' fees and expenses of the Relator against the DEFENDANTS for violations of the False Claims Act as set out in Counts I through VI. The violations arise from DEFENDANTS' actions which caused Medicare and the State Medicaid Programs to pay grossly inflated prices for DEFENDANTS' prescription drugs. This Fourth Amended Complaint encompasses all those prescription drugs and biologicals with respect to which DEFENDANTS violated the False Claims Act during the relevant time period by any of the means described herein, including, but not limited to, the prescription drugs and biologicals identified herein unless otherwise included by the Relator in a separate action under the False Claims Act.

2. The Medicare and State Medicaid Programs pay claims for the prescription drugs at issue herein only if three distinct requirements are met. First, the pharmaceutical drug manufacturer must make price and cost information about the prescription drug publicly available. Second, the program must elect to cover the prescription drug when medically necessary. Third, the physician, pharmacy or other health care provider who purchases the prescription drug must confirm that it was administered or dispensed to an eligible person covered by the applicable program. In some cases, most notably that of the Texas Medicaid Program, pharmaceutical manufacturers must report costs and prices directly to the state program to satisfy the price disclosure requirement.

3. This false claims action reveals an intentional scheme by DEFENDANTS to arrange financial inducements aimed at specialized physicians ([redacted]), clinics and pharmacies to increase sales of DEFENDANTS' prescription drugs which are reimbursed by Medicare and the State Medicaid Programs (sometimes collectively referred to herein as "Medicare/Medicaid"). The particular prescription drugs [redacted] at issue here are hereinafter referred to as the "specified drugs". The DEFENDANTS, participating in what amounts to a kickback scheme, create financial inducements by falsely inflating their reports of the price and cost of the specified drugs and by offering inducements such as free goods, direct monetary payments and rebates, thus causing Medicare/Medicaid to pay inflated reimbursements to the specialized physician, clinic or pharmacy (collectively "the Providers") providing the covered drug to the drug recipient. The financial inducements arranged by the DEFENDANTS are intentionally concealed so that Medicare/Medicaid will not benefit from the true prices in the marketplace. The DEFENDANTS were fully aware of the Medicare and Medicaid reimbursement methodologies and of the fact that Medicare/Medicaid was required to use drug manufacturers', including the DEFENDANTS', reported drug prices and costs in establishing Provider reimbursement amounts. Each DEFENDANT, had it so chosen, could have reported prices and costs for the specified drugs that fairly and reasonably reflected the prices actually being charged and paid in the marketplace. The DEFENDANTS were also free to elect not to report prices and thus not have their drugs covered by Medicare/Medicaid. Rather than choose either of these options, each of the DEFENDANTS has knowingly opted to report inflated prices and costs for the express

purpose of creating a "Spread" between the resulting Medicare/Medicaid reimbursement amounts and the prices actually being charged to the Providers. The Spread served as an inducement to Providers to purchase the specified drugs. Providers would then apply for reimbursement for such drugs under Medicaid and Medicare, and receive inflated reimbursement amounts from the Medicaid and Medicare programs pursuant thereto. This was a result which DEFENDANTS not only foresaw, but fully intended.

4. The DEFENDANTS were fully aware that the Medicare and State Medicaid Programs were required by their reimbursement policies to use drug manufacturers', including DEFENDANTS', reported drug prices and costs in calculating reimbursement amounts.

5. As a result of the fraudulent and illegal acts alleged herein, DEFENDANTS have reaped millions of dollars in illegal profits at the expense of the federal and State governments and directly contributed to the soaring cost of providing prescription drugs for the nation's elderly and poor.

A. THE MEDICAID AND MEDICARE FRAUD ARISING FROM DEFENDANTS' FALSE PRICE AND COST REPRESENTATIONS INVOLVING SPECIALIZED PHYSICIANS AND PHARMACIES AND INFUSION DRUGS

6. All fifty states have chosen to provide prescription drug coverage pursuant to Medicaid, the federal medical assistance program for the poor which both the federal and state government fund and which each state administers pursuant to federal statutes, regulations and guidelines. Additionally, "Part B" of the Medicare Program (which covers certain outpatient procedures for those over age 65, persons who are disabled and persons who have end stage renal disease), provides coverage for certain drugs which

cannot be taken by mouth or self-administered and for a small number of oral drugs including some chemotherapy and anti-emetic drugs.

7. This action focuses only on the Medicare/Medicaid reimbursement for the ingredient costs of the prescription drugs at issue herein and not on reimbursement for the administration or dispensing of such drugs. Medicare and Medicaid reimbursement for ingredient costs involves separate payments, using different methodologies, than for reimbursement for professional fees associated with administering and dispensing the prescription drugs.

8. The drugs at issue in this case are reimbursed by both Medicaid and Part B of Medicare. These drugs are ordinarily prescribed by specialized physicians for the treatment of serious illnesses, including respiratory diseases, [redacted]. They are generally available only through a hospital, specialized physician or a specialized pharmacy. [redacted] The other drugs at issue include, but are not limited to, [redacted] drugs used for inhalation therapy. [redacted] The Medicare beneficiaries and Medicaid recipients who receive the specified drugs are usually extremely ill. The physicians prescribing these drugs are in a unique relationship with the DEFENDANTS because they cannot only prescribe the drugs, they can also directly provide and

administer or arrange for the provision and administration of the drugs. They then apply for reimbursement from Medicare or Medicaid for the drug.

9. By reporting falsely inflated costs and prices for the specified drugs to Medicaid/Medicare, the DEFENDANTS created a "Spread" between the inflated acquisition cost that they caused the Medicare/Medicaid Programs to calculate and use for reimbursement purposes and the actual cost of the drug to the Provider. This "Spread", which constituted an unlawful financial inducement arranged by the DEFENDANTS, directly benefitted the DEFENDANTS because it caused Providers to order the DEFENDANTS' drugs.

10. With respect to Medicaid, at least half of the amounts paid by the States consisted of federal funds from which the States were required to pay claims based upon the drug's Estimated Acquisition Cost ("EAC") to the pharmacy submitting the claim. 42 CFR §447.331. The DEFENDANTS knew that each of the States' Medicaid Programs had implemented a mechanism to estimate the acquisition cost of prescription drugs to a pharmacy. Most states used the DEFENDANTS' representation of their Average Wholesale Price ("AWP") (hereinafter sometimes referred to as "AWP STATES") and some States, including but not limited to, Alabama, Colorado, Florida, Maryland, Massachusetts, Ohio and Rhode Island used the DEFENDANTS' representation of the prices they charged wholesalers for the specified drugs. The DEFENDANTS made their false price representations both directly to the States and indirectly through one or more of several drug price reporting compendia including First DataBank, Medical Economics

and Medi-Span, that assemble drug price data and which State Medicaid Programs utilized in establishing reimbursement amounts.

11. Throughout the relevant time period, Medicare's reimbursement was calculated with reference to a given drug's reported AWP in the case of single source drugs and biologicals and the median AWP in the case of multiple-source drugs and biologicals. The DEFENDANTS made false representations of prices and costs for the specified drugs directly to Medicare Carriers and Durable Medical Equipment Regional Carriers ("DMERC's") which approve and pay Medicare claims; and indirectly through the drug price and cost reporting compendia such as First DataBank, Medical Economics, and Medi-Span which Medicare utilized in establishing reimbursement amounts.

12. The DEFENDANTS knew that the Medicare and State Medicaid Programs intended to base their payments of "reimbursement" for the specified drugs on reasonable estimations of the drug's cost and that Medicare/Medicaid utilized the falsely inflated prices and costs reported by the DEFENDANTS in estimating reimbursement.

13. The DEFENDANTS were well situated to mislead the Medicare and State Medicaid Programs because the DEFENDANTS reported truthful prices and costs for many drugs that are not the subject of this action.

14. The "Spreads" which DEFENDANTS created between the reimbursement amounts that they caused the Medicare/Medicaid Programs to calculate and use for reimbursement purposes and the actual cost of the drug to Providers, were large and often enormous (over 1000% in some instances). DEFENDANTS' reported costs and prices for the specified drugs became mere marketing tools employed to increase sales while

bearing no relationship whatsoever to the actual prices Providers were paying for the specified drugs. DEFENDANTS thus duped the Medicare/Medicaid Programs into paying claims for the specified drugs at inflated amounts in order to increase the DEFENDANTS' sales and market share. In short, the DEFENDANTS falsely reported the price and cost of their specified drugs in order to cause Medicare/Medicaid to unwittingly fund unlawful kickbacks to Providers.

15. The DEFENDANTS thus wrongfully exploited the Medicare and State Medicaid Programs by knowingly causing them to pay Providers grossly inflated amounts that far exceeded a reasonable reimbursement amount based on an estimation of costs. This wrongful exploitation by DEFENDANTS caused the United States to incur single damages in excess of Ten Million Dollars for which the UNITED STATES and States Medicaid Programs are entitled to recover treble damages plus up to Ten Thousand Dollars per false claim, interest, costs and attorneys' fees.

SECTION NO. 2

THE PARTIES

16. The Plaintiff in this action is the UNITED STATES. At all times material to this civil action, the United States Department of Health and Human Services ("HHS"), the Health Care Financing Administration ("HCFA"),and its successor agency the Centers for Medicare and Medicaid Services ("CMS") and The Bureau of Program Operations ("B.O.") were agencies and instrumentalities of the UNITED STATES and their activities, operations and contracts in administering the Medicare program were paid from UNITED STATES' funds. The UNITED STATES and its subcontractors performing on behalf of the UNITED

STATES provided Medicare benefits to qualified beneficiaries which included payment of claims for the prescription drugs specified herein manufactured by the DEFENDANTS and utilized the false and fraudulent price and cost representations made by the DEFENDANTS in approving and paying claims.

17. The States, United States Territories, and the District of Columbia provided Medicaid benefits to qualified recipients which included payment of claims for the prescription drugs specified herein manufactured by the DEFENDANTS and utilized the false and fraudulent price and cost representations made by the DEFENDANTS in approving and paying claims. A significant percentage (at least 50%) of said Medicaid reimbursement was paid from United States Government funds pursuant to 42 U.S.C. § 1396(b).

18. The Relator, VEN-A-CARE, is a corporation organized under the laws of the State of Florida, with its principal offices in Key West, Florida. The Relator's principal officers and directors include Zachary T. Bentley and T. Mark Jones, who are each citizens of the United States and reside in Key West, Florida. The Relator is a pharmacy and is licensed to provide prescription drugs [redacted] specified in this Fourth Amended Complaint and has been, during the relevant period of this Complaint, a Medicare Part B supplier and a Florida Medicaid provider. The Relator has standing to bring this action pursuant to 31 U.S.C. §3730(b)(1). The information upon which these allegations are based was voluntarily provided by the Relator to the Federal Government prior to June 23, 1995 and thereafter has been frequently supplemented by the Relator.

19. VEN-A-CARE's principals were aware that Medicare and Medicaid reimbursed for drugs at amounts that were intended to be based on an estimation of cost and not provide for huge windfall profits at the GOVERNMENT's expense. VEN-A-CARE attempted to alert the responsible state and federal government officials to the scheme being perpetrated by the DEFENDANTS. However, the government agencies lacked sufficient resources and expertise to adequately respond. Accordingly, the Relator commenced this action based upon its original source information.

20. [redacted]

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[redacted]

28. [redacted]

[redacted]

29. [redacted]

30. The DEFENDANT, DEY, INC. ("DEY"), is a corporation organized under the laws of Delaware with its principal offices in Napa, California. At all times material to this civil action, DEY has transacted business in the Federal Judicial District of the Southern District of Florida by, including but not limited to, selling and distributing its drugs, including those identified in this Complaint, to purchasers within the Southern District of Florida. The DEFENDANT EMD PHARMACEUTICALS, INC. ("EMD") is a corporation whose headquarters are located in Durham, North Carolina. EMD is the sole shareholder of DEY. DEFENDANT LIPHA, S.A. ("LIPHA") is a corporation based in Lyon, France. LIPHA is the sole shareholder of EMD. DEFENDANT MERCK-LIPHA, S.A. ("MERCK-LIPHA") is a corporation based in Lyon, France. MERCK-LIPHA is the sole shareholder of LIPHA. DEFENDANT MERCK KGaA ("MERCK") is a German company based in Darmstadt, Germany. MERCK is the sole shareholder of MERCK-LIPHA. To the extent the acts of DEY at issue herein were performed by or otherwise attributable to EMD, LIPHA, MERCK-LIPHA or MERCK, or to any subsidiary or affiliate of any of these four defendants, then

judgment should be entered against EMD, LIPHA, MERCK-LIPHA or MERCK where appropriate.

31. [redacted]

32. [redacted]

33. [redacted]

[redacted]

34. [redacted]

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35. [redacted]

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36. [redacted]

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44. [redacted]

45. [redacted]

[redacted]

46. [redacted]

47. Any and all acts alleged herein to have been committed by any or all of the DEFENDANT DRUG MANUFACTURERS were committed by said DEFENDANTS'

officers, directors, employees, or agents who at all times acted on behalf of their respective DEFENDANT DRUG MANUFACTURER.

SECTION NO. 3

JURISDICTION & VENUE

48. Jurisdiction is founded upon the Federal False Claims Act (the "Act" or the "False Claims Act"), 31 U.S.C. §3729-32, specifically 31 U.S.C. §3732, and also 28 U.S.C. §§1331, 1345.

49. Venue in the Southern District of Florida is appropriate under 31 U.S.C. §3732(a) and sufficient contacts exist for jurisdiction in that each of the DEFENDANTS transacted business in the Southern District of Florida by selling directly or through wholesalers their prescription drugs, including those identified in ths Complaint, in the Southern District of Florida which the respective DEFENDANTS knew would be supplied to Medicare beneficiaries and Medicaid recipients and knew claims for reimbursement with respect to DEFENDANTS' specified drugs would be made by Medicaid and Medicare Providers.

50. A copy of the initial Complaint and this Fourth Amended Complaint and written disclosure of substantially all material evidence and information the Relator possesses were served on the Government pursuant to Rule 4(i)(1)(A) and (B), Fed.R.Civ.P., prior to the filing of the initial Complaint and this Fourth Amended Complaint **in camera and under seal** by delivering a copy of the initial Complaint and this Fourth Amended Complaint, material evidence and information to the United States Attorney for the Southern District of Florida and by sending a copy of the initial Complaint and this

Fourth Amended Complaint, material evidence and information by certified mail to the Attorney General of the United States at Washington, District of Columbia.

SECTION NO. 4

HOW DRUG MANUFACTURERS' PRICE AND COST REPRESENTATIONS ARE OBTAINED BY THE MEDICARE AND STATE MEDICAID PROGRAMS WHICH THEN UTILIZE THEM TO CALCULATE DRUG REIMBURSEMENT AMOUNTS

51. Prescription drug manufacturers, including the DEFENDANTS, the Medicare and Medicaid Programs, drug price and cost reporting services, hospitals, pharmacies, physicians, wholesalers, third party payors and administrators (i.e. insurance companies), governmental health benefit plans (i.e. federal and state employees) and others involved in the health care industry communicate about drug prices and costs by describing the price and cost with terms such as:

a) Average Wholesale Price ("AWP")

b) Wholesaler Acquisition Cost ("WAC")

c) List Price

d) Direct Price ("DP")

e) Wholesale Net Price

52. Average Wholesale Price ("AWP") is the drug price most commonly utilized by the healthcare industry and by third party payors, including the Medicare and State Medicaid Programs, to calculate the reimbursement amount for a given drug.

53. During the time period covered by this Complaint until January 1 1998, Medicare based its reimbursement for prescription drugs, including the drugs at issue, on

the manufacturers' published AWP for patented ("single source") drugs as represented by the manufacturer, and at the median published AWP, as represented by the manufacturers, for drugs with generic equivalents and for biologicals. Pursuant to Congressional investigation, and in an effort to arrive at reasonable Medicare drug reimbursement amounts, the Federal government changed the Medicare drug reimbursement formula pursuant to the Balanced Budget Act of 1997. Consequently, from January 1, 1998 until December 31, 1998, Medicare based its reimbursement for drugs at 95% of the published AWP for single source patented drugs and biologicals as represented by the manufacturer, and at 95 % of the median published AWP for all generic forms of a drug (or biological). Since January 1, 1999, Medicare has also considered the average wholesale price of brand forms of drugs when reimbursing for multiple source drugs and biologicals as discussed, infra.

54. The States' Medicaid programs are required by 42 CFR §447.331 to reimburse Providers at the Provider's Estimated Acquisition Cost ("EAC"). CMS, which must approve all State reimbursement plans for prescription drugs, has approved approximately 44 states' plans (plus that of Washington, D.C.) whose methodology for arriving at the Provider's EAC includes discounting a percentage off of the published AWP prices. This discounting ranges from Alaska and California, whose state formula is AWP minus 5%, to Illinois, whose state formula is AWP minus 12%. About fifteen states' formulas (plus that of Washington D.C.) are AWP minus 10%. Texas uses price representations obtained directly from drug manufacturers. About four states' formulas are WAC plus a percentage or an AWP discount/WAC hybrid.

55. Medical Economics, Inc., the Hearst Corporation and Medi-Span are nationally recognized companies that specialize in gathering drug pricing and cost information including Average Wholesale Price ("AWP"), Wholesaler Acquisition Cost ("WAC") and Direct Price ("DP").

56. Medical Economics, Inc. annually publishes a book entitled *Drug Topics Red Book*, (along with addendums to that book), which expresses drug prices and costs in terms of AWP. Medical Economics, Inc. also publishes a monthly update that contains current packaging and pricing data expressed in terms of AWP on the most widely prescribed drugs in the United States together with any updated prices expressed in terms of AWP for new products.

57. The Relator's information provided to the Government reveals that approximately 90% of all Medicare Carriers contracted by CMS to process Medicare Part B reimbursement claims use the AWPs as represented in Medical Economics annual *Drug Tropics Red Book* publication and the *Red Book* monthly updates in determining the reimbursement amounts for Medicare prescription drug claims.

58. Additionally, the DEFENDANTS regularly make representations of false price and cost information directly to the Carriers.

59. The Hearst Corporation, through its First DataBank Division, annually published until 1997 a book entitled *the First DataBank Blue Book* that expressed drug prices and costs in terms of AWP, Suggested Retail Price ("SRP") and Direct Price. Throughout the relevant time period First DataBank (sometimes referred to herein as "FDB") has also offered an entirely automated database service through which the

DEFENDANTS published their representations in the form of AWP, Direct Price and Wholesale Net/WAC.

60. First DataBank's automated service provides drug prices and costs for approximately 60,000 national drug code numbers ("NDC" numbers) comprising different drugs, sizes and strengths expressed in terms of AWP, WAC and Direct Price. The Relator's investigation has determined that more than 90% of the States' Medicaid Pharmacy Programs have utilized the AWPs and WACs as represented by First DataBank through either the Blue Book or First DataBank's automated services in determining reimbursement amounts for Medicaid prescription drug claims.

61. Medi-Span provides drug prices and costs for approximately 60,000 NDC numbers comprising different drugs, sizes and strengths through an electronic or automated service expressed in terms of AWP, Direct Price and WAC. The Relator's investigation has determined that only the State of New York's Medicaid Program uses Medi-Span's automated service in determining reimbursement amounts for New York Medicaid prescription drug claims. Medi-Span was acquired by the Hearst Corporation/First DataBank in January 1998 and was subsequently divested to Lippincott, Williams & Wilkins, a subsidiary of Wolters Kluwer, in January, 2002. From the beginning of 1998 through 2001, therefore, First DataBank included Medi-Span.

62. In determining the drug pricing data which they report, First DataBank, Medical Economics and Medi-Span all receive and rely upon the respective drug manufacturers', including the DEFENDANTS', representations of their drug prices and costs.

63. First DataBank, Medical Economics and Medi-Span all report drug prices that include a representation of the drugs' AWP.

64. The Relator's investigation has determined that drug manufacturers, including the DEFENDANTS, provide First DataBank, Medical Economics and Medi-Span with the specific prices and costs of their drugs and instructions, if necessary, expressed in a manner that allows the price reporting companies to establish the necessary pricing information for publication that is utilized by Medicare, Medicaid and others in determining reimbursements for prescription drugs.

65. During the relevant time period of this Complaint, a form entitled "New Product Submission Form" has been provided by First DataBank to drug manufacturers to transmit information including their prices to First DataBank. The form permits drug manufacturers to submit prices expressed in terms of Wholesale (Distributor) Price, Direct Price and AWP Price. After causing new products to be added to a national drug data formulary maintained by First DataBank, drug manufacturers, including DEFENDANTS, thereafter provided additional updated price representations such as Wholesale Net Price, Suggested Retail Price, Direct Price and/or AWP Price. Wholesale (Distributor) Price, Wholesale Net Price and WAC were represented to be the same price by the DEFENDANTS.

66. During the relevant time period of this Complaint, forms entitled "Product Listing Verification" and "New Product Information Form" have been provided by Medical Economics/*Red Book* to drug manufacturers to transmit information including their prices to Medical Economics / *Red Book*. The forms permit drug manufacturers to submit prices

expressed in terms that include, but are not necessarily limited to, AWP. Drug manufacturers, including DEFENDANTS, provide updated price and cost representations to Medical Economics Red Book expressed in terms that include, but are not necessarily limited to, AWP.

67. Each of the DEFENDANTS has been the source of the price and cost information reported by First DataBank, Medical Economics and MediSpan to the Medicare and States' Medicaid Programs at all times at issue in this action. The Relator reported its information to the Government, including specific identification of representatives of First DataBank and Medical Economics to whom such information was reported. Thereafter, the Government conducted an investigation which confirmed the information supplied by the Relator including the information that each of the DEFENDANTS has repeatedly and systemically communicated with First DataBank, Medical Economics and Medi-Span with the express purpose and effect of causing First DataBank, Medical Economics and Medi-Span to report prices and costs of the specified drugs in amounts set by the DEFENDANTS.

68. The DEFENDANTS also regularly make direct representations of false price and cost information directly to the various state Medicaid agencies that are relied upon in approving and paying claims.

SECTION NO. 5

THE ROLE OF THE DRUG WHOLESALER

69. The majority of the DEFENDANTS' drugs, including the specified drugs at issue in this action, are distributed through drug wholesalers who resell and distribute the drugs to hospitals, pharmacies, physicians and clinics.

70. Four companies, McKesson Drug, Cardinal, Bergen Brunswig and Ameri-Source have comprised approximately eighty (80%) of the over $70 billion dollar annual wholesale drug market during the relevant time period of the Complaint. On August 29, 2001, Bergen Brunswig and AmeriSource merged to form AmeriSource Bergen Corporation. Wholesalers generally sell to any person or entity (i.e. pharmacies, physicians and hospitals) who can lawfully purchase prescription drugs.

71. Wholesalers purchase the specified drugs at prices that are unilaterally set and controlled by the DEFENDANTS. The wholesalers in turn add a percentage (commonly referred to as an "up-charge") to the price to cover the wholesaler's expenses such as warehousing, delivery, billing and collections and to provide a profit. The percentage of up-charge is negotiated between the pharmacy and the wholesaler and is usually based on the pharmacy's purchasing volume. By way of example, the Relator's up-charge from McKesson during the time period covered by this Complaint was 6.5%.

72. Throughout the time period covered by this Complaint, each DEFENDANT closely monitored and was aware of the prices it charged wholesalers for its drugs, including the specified drugs, and the impact which rebates, charge-backs and any other off-price discounts had upon the net price of the drug to the wholesaler.

73. Throughout the time period covered by this Complaint, each DEFENDANT closely monitored and was aware of the prices which wholesalers charged Providers for its drugs and the net impact which rebates, volume discounts and any other off-invoice discounts had upon the net price to the Provider.

74. The DEFENDANTS' "charge-back" arrangements with wholesalers were used in a manner which facilitated the reporting of inflated costs and prices for drugs including some of the drugs in this case. In the charge-back arrangements at issue here, the drug manufacturer directly negotiates with entities such as a group purchasing organization or managed care organization ("contract customers"), for the sale of a given drug at a negotiated contract price. The wholesaler then agrees to buy from the DEFENDANT at an inflated price the drug which is destined for the contract customer. The wholesaler then sells the drugs to the contract customer at a price which is lower than (in some cases by 50% or more) what the wholesaler ostensibly paid for the drug from the DEFENDANT. The manufacturer, meanwhile, credits the wholesaler for the difference between the inflated cost to the wholesaler and the actual price received by the wholesaler from the contract customer, as well as pays the wholesaler an up-charge. The DEFENDANTS' use of the "charge-back" device in this manner permitted the DEFENDANTS to control prices charged by wholesalers while falsely reporting an inflated wholesaler cost by excluding the often significant impact of the charge-back on the net effective wholesale acquisition cost.

75. In order to monitor the wholesalers' compliance, the DEFENDANTS require all drug wholesalers to periodically (generally quarterly) report back to the DEFENDANTS all prescription drug sales by NDC number, provider name and sales price.

76. [redacted]

77. The DEFENDANTS negotiate prices for their prescription drugs individually with hospitals, Government entities, closed pharmacies, mail order pharmacies, HMO's, physicians, and with group purchasing organizations (" GPO's") who represent groups of smaller Providers. GPO's provide members lower cost products by negotiating prices for specific drugs from manufacturers. The GPO member is able to purchase the drugs at the negotiated price either in some cases directly from the manufacturer or from a wholesaler that has a charge-back agreement with the specific manufacturer. Numerous wholesalers have participated to some degree in the DEFENDANTS' charge-back system. Acceptable membership in the GPO's is controlled by the DEFENDANTS. The GPO's are required to send periodic detailed reports of membership compliance to the DEFENDANTS.

SECTION NO. 6

BACKGROUND OF HOW UNITED STATES' MONIES ARE PAID FOR DRUG CLAIMS UNDER "PART B" OF THE MEDICARE PROGRAM

78. HHS, through CMS, provides health insurance benefits to aged and disabled Americans pursuant to the provisions of the Medicare program, Title XVIII of the Social Security Act, 42 U.S.C. §1395 et seq.

79. The Medicare program provides covered health care benefits to certain targeted populations such as those persons who are over age 65, persons who are disabled, and persons who have end stage renal disease.

80. The Medicare program is divided into two distinct parts: (A) Medicare Part A (Hospital Insurance for the Aged and Disabled) which covers services and goods furnished by hospitals, home health agencies, hospices, and skilled nursing facilities; and (B) Medicare Part B (Supplementary Medical Insurance for the Aged and Disabled) which covers physician services, and a range of other noninstitutional services, such as durable medical equipment ("DME"), oxygen concentrators, diagnostic laboratory tests, X-rays, and certain limited drug products and supplies.

81. This case focuses on the Medicare Part B's limited benefit for drugs which are provided either: (a) incident to a physician's service and cannot generally be self-administered; or, (b) in conjunction with the medical necessity of an infusion pump or nebulizer or other DME device payable under Medicare's DME benefit. Because this limited drug benefit is provided on an "incident to" a physician's service basis or in conjunction with the medical necessity of a DME device, Congress' statutes and the

corresponding HHS regulations and CMS policies have sought to limit Medicare's payments for claims for the drugs at issue to a reasonable amount based upon the cost of the drug. This is due, in part, to the fact that the Medicare program is already paying for the physicians' professional fees and for the covered DME equipment. The exorbitant profits created by the DEFENDANTS' false price and cost representations have totally thwarted the fundamental requirements of the Medicare Program and States' Medicaid Programs that payment of claims for the specified drugs be limited to reasonable amounts to cover the added cost of the drugs.

82. CMS administers the Medicare program. CMS awards cost-reimbursement contracts to private companies (hereinafter referred to as "Contractors") to evaluate and to process Medicare beneficiaries' claims for payment on behalf of CMS. Under Part A, CMS refers to contractors as "intermediaries." Under Part B, CMS refers to contractors as "carriers" and durable medical equipment regional carriers ("DMERCs"). Under Part B, CMS pays the carriers and the DMERCs to process claims for covered benefits supplied to eligible beneficiaries and to make payments to the Providers or to the Medicare beneficiaries for the covered services rendered under Medicare Part B. 42 U.S.C. §1395(j) et. seq.

83. Congress has mandated that the Medicare Program pay no more than eighty percent (80%) of: (1) the reasonable cost of drugs covered under Part B pharmaceutical claims from federal funds through 1997 and (2) no more than 95% of the drug's Average Wholesale Price, after 1997. 42 U.S.C. §1395(l) et seq.

84. Medicare Regulation 42 CFR §405.517 (contained in Subpart E - - Criteria For Determining Reasonable Charges) sets out the methodology to determine the charge for payment of claims for drugs and biologicals. Prior to January 1, 1998, the methodology for single source drugs and biologicals provided therein was based on the lower of estimated acquisition cost or the national average wholesale price of the drug or biological. The methodology for multiple source drugs was based on the lower of the estimated acquisition cost or the wholesale price that is the median price for all sources of the generic form of the drug or biological. This regulation provided instructions to be used by the Part B Carriers and DMERCs on how the estimated acquisition cost was to be determined. The instructions stated that the estimated acquisition cost was to be based on surveys of actual invoice prices of drugs paid by the Providers. The regulation also stated that the Medicare Part B Carriers and DMERCs may consider such other factors as inventory, waste and spoilage in calculating the estimated acquisition cost of the drug but did not provide for profit on the drug itself.

85. The Medicare program has been unable to determine actual acquisition costs for the drugs at issue in this case. Therefore, until January 1, 1998, Medicare paid claims based upon the national average wholesale price for single source patented drugs or biologicals as represented by the manufacturer, and at the median national average wholesale price for all generic forms of a drug or biological, as represented by the manufacturers, for drugs or biologicals with generic equivalents. From January 1, 1998 until December 31, 1998, under 42 C.F.R. § 405.517, Medicare paid claims based upon 95% of the national average wholesale price for single source patented drugs and

biologicals as represented by the manufacturer, and at 95 % of the median national average wholesale price of all generic forms, as represented by the manufacturers, for drugs and biologicals with generic equivalents.

86. Effective January 1, 1999, the methodology for multiple source drugs and biologicals changed under 42 C.F.R. § 405.517 (but not any other aspect of the reimbursement methodology) to the extent that Medicare now pays 95% of the lesser of the median average wholesale price for all sources of the generic forms of the drug or biological or the lowest average wholesale price of the brand name form of the drug or biological. 42 C.F.R. §405.517. Consideration of the AWP for all generic forms of a drug with generic equivalents until 1999 and consideration of the AWP for all generic and brand forms of a drug with generic equivalents from 1999 until the present to determine the reimbursement amount are collectively referred to herein as the "J Code Medicare reimbursement methodology".

87. To arrive at the median average wholesale price, the Carrier first obtains the AWP amounts as reported for all generic versions of a given drug from the current Red Book. Second, the Carrier arrays the listings from the most expensive to the least expensive of all the manufacturers' generics. Third, the Carrier finds the median AWP. The Relator's investigation has determined that when the array contains an even number of reported AWP's, some Carriers choose as the median the higher listing of the two AWP's in the middle of the array and some choose the lower.

88. Part B drug claims are submitted either in hard copy form or through an electronic claims filing procedure.

89. Providers submit claims for payment to the Medicare Program for the specified drugs at issue in this case using HCFA's Common Procedure Coding System ("HCPCS" or the "J Code System"). The HCPC system for pharmaceuticals is a 5 digit alphanumeric code, such as [redacted]; HCPCS Code [redacted].

90. HCFA requires all Part B Carriers and the DMERCs to report to HCFA Central quarterly claims activity by HCPCS Code for all drugs submitted by Providers for reimbursement by the Medicare Program.

91. Beneficiaries' claims are processed by the carriers as either "assigned", those claims for which payment is made directly to the provider, or "unassigned", those claims for which payment is made directly to the beneficiaries.

92. All or nearly all drug claims for the charges at issue are made on an assigned basis.

93. During the early 90's the Medicare Carriers' attempted to survey physicians' actual invoice prices paid for drugs to comply with the regulation 42 CFR §405.517 but were stopped by a complaint filed by the American Society of Clinical Oncologists ("ASCO") with the Executive Office of Management and Budget asserting that the Paperwork Reduction Act had been violated. A subsequent effort by CMS to design a new survey to determine physicians' actual invoice costs was also stopped by ASCO. ASCO complained that the actual prices being paid were discounts and confidential in nature and that the survey had other flaws.

94. At all times at issue in this case, the Medicare program used the drug price and cost information represented by the DEFENDANTS to determine reimbursement amounts.

SECTION NO. 7

BACKGROUND OF HOW UNITED STATES' MONIES ARE PAID FOR DRUG CLAIMS UNDER THE STATE MEDICAID PROGRAMS

95. The United States Government partially funds state sponsored medical assistance programs for the poor pursuant to Title XIX of the Social Security Act, 42 U.S.C. § 1396 et seq.

96. Benefits for drugs are optional but all states have opted to provide Medicaid drug reimbursement coverage.

97. The federal portion of States' Medicaid payments, Federal Medical Assistance Percentage ("FMAP") is based on a state's per capita income compared to the national average. The federal portion consists of a minimum of 50% up to a maximum of 83%. For example, Florida's FMAP contributed by the United States in 1995 was 56.28%.

98. The States, United States Territories and the District of Columbia are required to implement a State Health Plan containing certain specified minimum criteria for coverage and payment of claims in order to qualify for federal funds for Medicaid expenditures.

42 U.S.C. §1396a(a)(30)(A).

99. State Health Plans must, in part, provide for payment of claims for prescription drugs pursuant to a formula approved by the Secretary of HHS which determines the maximum allowable claim amount for each drug manufactured by each manufacturer whose prescription drugs qualify for Medicaid reimbursement based upon an estimation of the provider's acquisition cost plus a reasonable dispensing fee. 42 CFR §447.331.

100. CMS has approved approximately 44 state plans whose methodology for arriving at a provider's Estimated Acquisition Cost ("EAC") as required by 42 CFR §447.331 includes discounting a percentage off of the AWP prices, separately for each covered drug, as computed by or collected by and published by First DataBank (and by Medi-Span in the case of New York).

101. The Food and Drug Administration ("FDA") assigns National Drug Codes, called NDC numbers to identify each individual manufacturer and its drugs' strengths and sizes. NDC numbers are eleven digits, with the first five digits identifying the manufacturer or labeler, the next four digits identifying the product and the last two digits identifying the package size.

102. Providers are required to utilize the FDA's NDC numbers when submitting claims for reimbursement for drugs to the States' Medicaid programs.

103. The vast majority of States award cost-reimbursement contracts to private companies to evaluate and process Medicaid recipients' claims for payment. The States refer to these contractors as fiscal agents.

104. Prescription drug claims are submitted either in hard copy form or through an electronic claims filing procedure.

105. At all times at issue in this case, all of the States' Medicaid programs used the drug price and cost information represented by the DEFENDANTS to determine reimbursement amounts.

106. CMS has approved state plans whose methodology formulae for arriving at a pharmacy's estimated acquisition cost as required by 42 CFR §447.331 includes:

a) discounting a percentage off of the AWP prices as computed by or collected by and published by First DataBank ;

b) adding a percentage to the WAC prices as computed by or collected by and published by First DataBank ; and,

c) requiring the drug companies, including the DEFENDANTS, to certify their prices directly in writing to the Texas Medicaid Vendor Drug Program.

110. During the time period covered by this Complaint, the CMS-approved State plans for Medicaid reimbursement based on WAC have included, without limitation:

	Drug	Dispensing Fee
Alabama	WAC+9.2%	$5.40
Colorado	lesser of AWP-10% or WAC+18%	$4.08
Florida	WAC+7%	$4.23
Maryland	WAC+10%	$4.21

Massachusetts	WAC+10%	$3.00
Ohio	WAC+11%	$3.70
Rhode Island	WAC+5%	$2.85-$3.40
Illinois	WAC+8% (brand) WAC+12% (generic)	$3.30- $15.45

111. The Texas Medicaid Program has gone to exceptional lengths to verify that drug manufacturers, including the DEFENDANTS, provide truthful price and cost information for reimbursement purposes. The Texas Medicaid authorities, acting pursuant to 25 Texas Administrative Code §35.801, required the DEFENDANTS to certify, in writing, the accuracy of their price and cost representations as a condition to their drugs being covered for reimbursement.

112. The State of Texas pays reimbursement for drugs covered by its Vendor Drug Program at the lesser of the provider's usual and customary charge or Estimated Acquisition Cost ("EAC"). In Texas' Pharmacy Provider Handbook, EAC is defined as either the Wholesale Estimated Acquisition Cost ("WEAC") or the Direct Estimated Acquisition Cost ("DEAC"). WEAC is the estimated price paid by Providers purchasing a drug from a wholesaler. DEAC is the estimated price paid by a Provider purchasing the drug directly from the drug's manufacturer.

113. The State of Texas has calculated the WEAC reimbursement amounts by calculating: 1) the drug manufacturer's reported "price to wholesaler and/or distributor" plus 12% and 2) reported AWP minus a percentage, which percentage has varied throughout the relevant period of the Complaint, but has never exceeded 18%, and then selecting the

lesser of the two resulting amounts as the WEAC for payment of claims. DEAC reimbursement reflects the drug manufacturers' Direct Price as reported directly by the drug manufacturer. The Texas Medicaid Program has also often considered the amounts reported by Defendants through First DataBank as a check or point of comparison to determine if Defendants' representations should be reviewed for correctness.

114. The State of Texas required the DEFENDANTS to complete a specific form regarding the prices of their drugs. Immediately before the required signature by the DEFENDANTS' representatives is the following language:

> I hereby certify that the information submitted is correct to the best of my knowledge . . . I also agree to inform the Texas Department of Health of any changes in . . . price . . . within fifteen (15) days of such change.

Attached hereto as Exhibit "1" is a true and correct copy of a certification used by the Texas Medicaid Vendor Drug Program during the relevant time period of this Complaint.

115. Pharmacies are reimbursed for prescription drugs by the States' Medicaid Programs in accordance with:

1. the State's CMS approved plan (i.e. Massachusetts' WAC+ 10%);
2. the pharmacies' usual and customary charges to the general public; or,
3. the Federal Upper Limit ("FUL"), (which is inapplicable to all but a few of the specified drugs at issue in this Complaint), plus a reasonable professional or dispensing fee.

113. The States' Medicaid Programs also receive price and cost representations directly from the DEFENDANTS and use them to confirm the accuracy of price and cost in computing reimbursement amounts.

SECTION NO. 8

THE FALSE CLAIMS SCHEME

A. DEFENDANTS' SCHEME RESULTED IN MULTIPLE VIOLATIONS OF THE FALSE CLAIMS ACT

114. By knowingly reporting falsely inflated cost and price representations bearing no relation to the actual prices Providers had paid for the specified drugs, both directly to Medicare/Medicaid and indirectly by means of the various drug reporting compendia, the DEFENDANTS caused false claims for excessive reimbursement to be submitted to Medicare/Medicaid by Providers. Pursuant to this kickback scheme engineered by DEFENDANTS, Providers then received a windfall financial benefit from Medicare/ Medicaid in the amount by which the Government's approved "reimbursement" amount exceeded a reasonable estimate of the Provider's true acquisition cost. The DEFENDANTS are each liable therefore under the False Claims Act, 31 U.S.C. §§3729-3732.

115. The DEFENDANTS also caused the submission of false claims by actively marketing the Spread on their specified drugs to Providers. This financial inducement was in many cases enhanced by additional inducements such as free goods, discounts, rebates, direct money payments, off invoice pricing and deceptive invoicing, all of which increased the Spread by lowering the true price for the specified drugs.

116. Each DEFENDANT acted knowingly, as defined in the False Claims Act, in providing the false and misleading price and cost information and in marketing the Spread, which actions caused Medicare/Medicaid to pay claims for the DEFENDANTS' drugs in excessive amounts.

117. As the DEFENDANTS knew, when Providers purchased a drug for which the reported prices and costs were falsely inflated, not only would Providers receive excessive reimbursement under Medicaid for such drug but, in all likelihood, the Provider would receive excessive reimbursement under Medicare as well. Also as DEFENDANTS knew, this was true even in the case of multiple-source Medicare drugs because in addition to DEFENDANTS' own inflated reported AWPs, other drug manufacturers were falsely inflating their AWPs for competing versions of such drugs falling under the same HCPCS code. The DEFENDANTS were aware of the amount of excessive reimbursement which a Provider would receive under Medicare and Medicaid for their specified drugs.

118. DEFENDANTS inflated their reported price and cost information and marketed the "Spread" resulting therefrom, with the purpose and intent of increasing sales of their respective specified drugs to Providers. As a direct, foreseeable and proximate result thereof, they caused false claims for excessive reimbursement to be made to both the Medicare and Medicaid Programs. But for each DEFENDANT'S actions, Medicaid/Medicare would not have paid the excessive reimbursement amounts which were in fact paid for each DEFENDANT'S respective specified drugs. Each DEFENDANT is thus liable under the False Claims Act for each Medicare and Medicaid reimbursement

claim for its respective specified drugs which resulted in payment of a falsely inflated reimbursement amount.

119. Medicaid Drugs and Single Source Medicare Drugs -- As the DEFENDANTS knew, for any given drug under Medicaid, only that drug's reported price or cost was utilized to calculate the reimbursement amount, and not the reported price or cost of any competing brand or generic version of the same drug with a different NDC number. As the DEFENDANTS also knew, for any single source drug under Medicare, only that drug's reported AWP was utilized to calculate the reimbursement amount since no competing brand or generic version sharing the same HCPCS code existed.

120. Joint And Several Liability As To Multiple-Source Drugs Under Medicare --

(a) Each DEFENDANT which reported a falsely inflated AWP for its brand or generic version of a drug falling under a given HCPCS code is jointly and severally liable with every other DEFENDANT which reported a falsely inflated AWP for its version of the drug falling under that HCPCS code, for the sum of all falsely inflated reimbursement amounts paid to Providers under that HCPCS code. In particular: 1) each DEFENDANT knowingly engaged in the same wrongful conduct, namely, reporting an inflated AWP; 2) each DEFENDANT acted concurrently with other drug manufacturers in reporting falsely inflated AWPs; 3) each DEFENDANT knew, or at a minimum was recklessly indifferent to the fact, that other drug manufacturers were inflating their AWPs on their respective version of the drug; 4) it was foreseeable by each DEFENDANT that their wrongful conduct (reporting an inflated AWP) could, if combined with the same wrongful conduct on the part of another drug manufacturer(s), jointly cause an inflated reimbursement amount to be paid

to Providers for the drug; 5) the DEFENDANTS' wrongful conduct did in fact coalesce to jointly cause the payment of an inflated reimbursement amount for the drug; and 6) in each instance the harm resulting from DEFENDANTS' joint reporting of inflated AWP's was inflicted upon the same entity, namely, the Federal Government.

(b) DEFENDANTS knew the applicable drug reimbursement formula for multiple-source drugs and were aware, if not specifically, at least generally, of the amount of reimbursement which a Provider would receive under Medicare for their specified drugs. The DEFENDANTS also knew that other drug manufacturers were inflating their reported AWPs for such specified drugs as well and thus knowingly participated jointly in a scheme whereby Providers received excessive reimbursements for such specified drugs under Medicare. The DEFENDANTS had no legitimate business purpose for inflating the reported AWP's of their specified drugs. In fact, the DEFENDANTS only engaged in such a practice in order to illegally inflate the drug reimbursement amounts calculated and paid by both Medicare and the State Medicaid Programs, and to thereby increase sales of their respective specified drugs. With respect to each specified drug which was a multiple-source drug reimbursed under Medicare, DEFENDANTS that: 1) were sources of any brand or generic version of such drug falling under a given HCPCS code, and 2) knowingly reported inflated AWP information with respect to their versions of such drug, were therefore jointly and severally liable for the sum of the falsely inflated reimbursement amounts paid to Providers for all brand and generic versions of that multiple-source drug.

121. Joint And Several Liability As To Multiple-Source Drugs Under Medicaid –

(a) Many State Medicaid programs reimburse certain Providers, such as physicians, for multiple-source drugs using a methodology similar to the J Code Medicare reimbursement methodology described herein. To the extent that any DEFENDANT jointly with other drug manufacturer(s) caused inflated reimbursement amounts to be paid for any multiple-source drug under any such State Medicaid reimbursement methodology, each such DEFENDANT is jointly and severally liable for the total of the falsely inflated reimbursement amounts paid for all versions of such multi-source drug for the reasons set forth in the preceding paragraph.

(b) A few of the specified drugs are multiple-source drugs which are subject to a Federal Upper Limit ("FUL") for Medicaid purposes. Pursuant thereto, the reimbursement amount for such drugs has been capped at 150 percent of the published price for the least costly therapeutically equivalent version of the drug plus a reasonable dispensing fee. 42 CFR §447.331-333. Each DEFENDANT who manufactured a drug subject to an FUL, and reported a falsely inflated reported price or cost with respect to such drug is, therefore, jointly and severally liable (along with all other DEFENDANTS who engaged in the same wrongful conduct with respect to such drug) for the sum of all falsely inflated reimbursement amounts paid for all versions of that drug. In this regard, each such DEFENDANT: a) knowingly reported falsely inflated price and cost information with respect to such drug, b) knew the reimbursement methodology for a FUL drug, and c) knew that if it provided truthful price and cost information, that the reimbursement amount would not have been inflated beyond what the FUL was intended to allow. Each such DEFENDANT also knew, or was recklessly indifferent to the fact, that if the DEFENDANT reported an

inflated price or cost, it was foreseeable that the reimbursement amount, despite the FUL, would be excessive, particularly since the DEFENDANT knew, or had ample reason to suspect, that other drug manufacturers were falsely inflating their reported prices and/or costs for their respective version of such multiple-source drug.

122. Joint And Several Liability Arising From Drug Marketing Agreements – At various times certain DEFENDANTS entered into contractual relationships ("Drug Marketing Agreements"), with other drug companies to either: a) market and sell a drug which the other drug company manufactured or b) allow another drug company to market and sell a drug the DEFENDANT manufactured. In the case of drugs subject to such an agreement, when Providers sought Medicare/Medicaid reimbursement, the reimbursement amount was generally calculated with reference to the drug manufacturer's reported prices and costs. When these reported prices and costs were falsely inflated therefore, the drug companies with marketing rights, together with the drug manufacturers, enjoyed the benefit of the resultant inflated reimbursement amounts in the form of increased sales. Drug companies with marketing rights knew, or at a minimum were recklessly indifferent to the fact, that drug manufacturers had falsely inflated the reported prices and costs of the drugs covered by a Drug Marketing Agreement. In essence then, when drugs subject to a Drug Marketing Agreement had falsely inflated reported prices and costs, both parties to such Drug Marketing Agreement were knowingly participating jointly in a scheme whereby Providers received excessive Medicare/Medicaid reimbursement for such drugs. Therefore, to the extent certain DEFENDANTS entered into such Drug Marketing Agreements to either grant or to receive marketing and selling rights to drugs with falsely

inflated reported prices and costs, they are each jointly and severally liable with the other party to such Agreement for the sum of the falsely inflated reimbursement amounts paid to Providers for such drugs.

123. The DEFENDANTS knew that Medicare/Medicaid would not pay or approve claims for the specified drugs if it were disclosed to Medicare/Medicaid that said claims were for amounts that included kickbacks.

124. The DEFENDANTS also knew that the Providers, in presenting claims for the specified drugs to Medicare/Medicaid, would not and did not disclose that the claim amounts included kickbacks.

125. The DEFENDANTS each carried out their scheme to defraud Medicare/Medicaid by knowingly providing false and misleading price information directly or indirectly to Medicare/Medicaid so that the Providers would be reimbursed in excessive amounts and thus be financially induced to prescribe and purchase the DEFENDANTS' specified drugs. The DEFENDANTS thus each participated in a fraudulent scheme to cause Medicare/Medicaid to pay and approve false claims in excessive amounts.

126. The claims in question are each false claims under the False Claims Act, in part, because they were each supported by and the payment amount determined from, the false and misleading price information provided by the DEFENDANTS in connection with their respective specified drugs.

127. The false claims at issue in this action were each claim for reimbursement submitted to Medicare/Medicaid by or on behalf of Providers that sought and received payment in excessive amounts because of false and misleading price and cost

representations made by the DEFENDANTS directly or indirectly to Medicare/Medicaid. The false claims at issue number in the tens of thousands, and were submitted by thousands of Providers nationwide throughout the relevant time period of the Complaint. Each claim is in the possession of Medicare or the applicable State Medicaid Programs.

128. For many of the specified drugs, the Relator has identified the false claims to the Federal government by: providing the truthful prices concealed from Medicare/Medicaid by the DEFENDANTS for each specified drug; providing information about the DEFENDANTS' exploitation of financial inducements to induce utilization of these drugs and specific identification information about these drugs and by providing the specific false price representations in question from which the Relator and the Federal government identified the specific false claims.

129. The damages sought herein include, but are not limited to, those arising from the false claims for the specified drugs set out in Sections 12 through 34 and elsewhere throughout this Fourth Amended Complaint. The damages sought herein also encompass all damages and penalties recoverable due to the false claim scheme of the DEFENDANTS alleged herein relating to all drugs of all sizes about which false price representations or records were used in connection with, considered or made available in, caused, aided or otherwise affected the presentment, payment or approval of false claims. These claims also encompass recovery of the funds paid for false claims due to the DEFENDANTS' false drug price representations, regardless of the Federal or State program that actually expended the funds, the person or entity that ultimately received the

funds or the person or entity from which the Federal government or the States ultimately recovers the funds.

130. Some of the information supporting the Relator's allegations is in the exclusive control of the DEFENDANTS, in particular, certain information relating to the actual prices of certain drugs taking into account the impact of rebates, charge-backs, discounts, bonuses, free goods and/or any other mechanism which lowers the ultimate cost of a drug to Providers.

B. THE NATURE AND IMPACT OF THE DEFENDANTS' FALSE CLAIM SCHEME

131. **DEFENDANTS' Actively Used the Spread as a Marketing Tool Directed at Providers to Promote Increased Sales of the Specified Drugs.** By means of, among other things, direct mailing, facsimile transmission and verbal communications by sales representatives, DEFENDANTS repeatedly and systematically promoted the inflated reimbursement amounts Providers would receive from both Medicare and Medicaid as a result of DEFENDANTS' inflated reported prices and costs.

132. [redacted]

a) [redacted]

[redacted]

b) [redacted]

c) [redacted]

133. **Defendants Create the False Price Spread to Induce Sales of Drugs Used to Treat Very Serious Medical Conditions**. The attached Exhibit 2 lists some of the DEFENDANTS' drugs and their approved FDA indications as published in the 1998 edition of *Drug Facts and Comparisons.* The percent of pricing fraud is represented by the mark-

up between the DEFENDANTS' AWP listing in the 1998 *Drug Topics* Red Book and Ven-A-Care's true 1998 wholesale cost for a common size.

134. **Defendants' Inflated Reports Of Prices And Costs Unlawfully Induce The Utilization Of The Specified Drugs.** The DEFENDANTS benefit directly from their false pricing scheme of concealing their true prices while making grossly inflated false and fraudulent representations of prices and costs by maximizing their products' sales volume, capturing market share for their products, and increasing utilization of their products by Providers. An example of how the DEFENDANTS directly benefit from their false pricing scheme is shown by data for the first quarter of 1997 from the State of Florida's Medicaid Program setting out Florida Medicaid's reimbursements paid to the customers of drug manufacturers and utilization of their products by their customers for the drug Albuterol Sulfate 0.083% Solution ("Albuterol"), a drug which is administered by inhalation or used for the treatment of respiratory illnesses.

135. The chart below sets out the number of reimbursed claims, VEN-A-CARE's cost per ml and "the Spread" between Medicaid reimbursement and true cost. A review of the chart clearly demonstrates that the vast majority of Providers utilize the manufacturer's drug with the greatest spread between the true Wholesale Acquisition Cost and the inflated false Wholesale Acquisition Cost reported by the drug manufacturer.

FALSE PRICING SCHEME - "THE SPREAD" FLORIDA MEDICAID REIMBURSEMENT (1st Quarter 1997) ALBUTEROL SULFATE SOLUTION 0.083%					
Manufacturer	VAC's Cost per ml	Florida Medicaid Reimbursement per ml	The Spread	# of claims	Reimbursement paid by Florida Medicaid
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Dey	$0.1125	$0.3531	$0.2406	9,792	$707,220.50
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

TOTAL REIMBURSEMENT BY THE STATE OF FLORIDA MEDICAID PROGRAM (January 1 through March 31, 1997)	$1,477,075.86

**	The use of the spread to falsify claims is evidenced by the fact that [redacted] and DEY's customers will receive a greater windfall by purchasing their product than they could if they somehow acquired the same product from [redacted] or [redacted] free of charge.

136. The DEFENDANTS' false claim scheme also affects utilization of specified drugs covered by Medicare, as evidenced by the history of the inhalation drug Ipratropium Bromide, the brand name of which is Atrovent. [redacted]. manufactured the brand Atrovent and a generic equivalent was not available until 1997. DEFENDANT DEY brought the new drug Ipratropium Bromide onto the market in 1998, however, it falsely represented that the generic price was equivalent to the brand when it was substantially less. The following chart reveals the spread created by the false price

representations of the generic manufacturers, including DEY, and the corresponding increase in Medicare utilization.

MEDICARE UTILIZATION FOR THE INHALATION DRUG IPRATROPIUM BROMIDE 0.02% SOL. HCPCS J7645 & (K0518)

YEAR	MEDICARE REIMBURSEMENT AMOUNT PER UNIT*	VAC COST PER MEDICARE UNIT**	"SPREAD" (PROFIT) $	"SPREAD" (PROFIT) %	MEDICARE EXPENDITURES
1995	$ 3.11 mg. ($0.62/ml)	$3.11	$0.00	0%	$14,426,108
1996	$ 3.75 mg. ($0.75/ml)	$3.26	$0.49	15%	$47,388,622
1997	$ 3.50 mg. ($0.70/ml)	$2.15	$1.35	63%	$96,204,639
1998	$ 3.34 mg.	$1.70	$1.64	96%	$176,887,868
1999	$ 3.34 mg.	$1.60	$1.74	108%	$253,400,414
2000	$3.34 mg.	$0.94	$2.40	255%	$347,527,960
2001	$4.34 mg.	$0.82	$2.52	307%	

* **Medicare Units were converted from ml's to mg's for the years 1995,1996 &1997. (5 ml=1 milligram) and 1998-2001 @95% of AWP**

** **VAC's cost were obtained from McKesson Drug Company published wholesale prices and do not include any common industry discounts or incentives or prices obtained through a group purchasing organization ("GPO").**

137. **Defendants' False Price Scheme Causes Over-Utilization Of Particular Drugs.** The grossly inflated payments unwittingly made by Medicare/Medicaid not only served as an inducement to Providers to purchase a particular manufacturer's product but also served to drive over-utilization. The Relator, prior to filing the initial Complaint in this

action, surveyed three national pharmacy Providers of Albuterol to determine their business practices for their sales of Albuterol to the Medicare and State Medicaid Programs. The Relator's principals used positions in an affiliated home health care company to pose as an interested customer. The Relator determined that the payment of kickbacks and/or split fees were commonplace between the pharmacies and home health care companies who could provide the pharmacies with patient referrals. One marketing scheme offered by one of the pharmacies was the automatic shipping of refills of Albuterol every month without verifying continuing need with the patient or physician in order to maximize the sales of Albuterol and reimbursement.

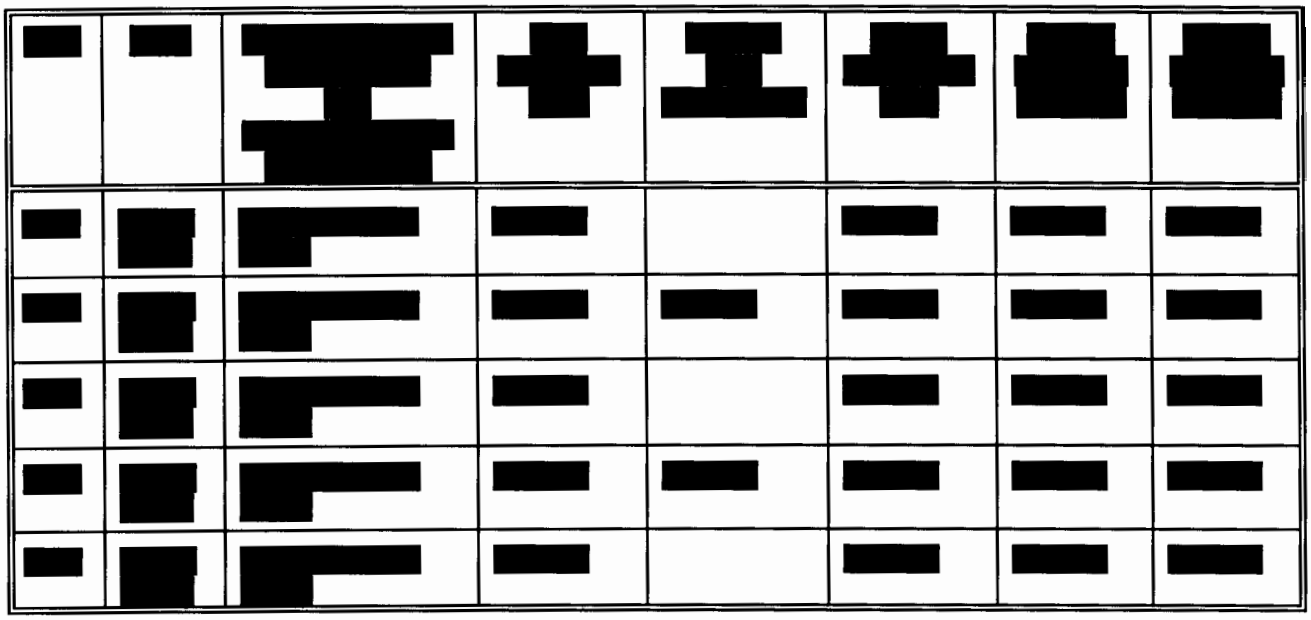
138. **The Inflated Prices And Costs On Many Drugs Was Of Such Magnitude That The Medicare Patient's 20% Co-Payment Exceeded The Cost Of The Drug To The Provider.** For many of the specified drugs, the DEFENDANTS' false representations of price and cost caused the Medicare Program to pay and approve claims at such exorbitant amounts that the 20% co-payment paid by the patient exceeded the true price of the drugs. In such instances, Medicare patients were in effect being entirely denied the prescription drug benefit to which they were legally entitled under Medicare. Exhibit 3 hereto provides examples of such drugs.

139. **Defendants' Inflated Price Reports Cause Some Generic Drugs To Be More Expensive Than The Brand Drug**. In many cases the DEFENDANTS' false claims scheme has caused the Government to pay claims for generic equivalents in amounts greater than the claims that would have been paid for the brand name version of the drug. The DEFENDANTS have thus deprived the Government of the expected savings arising

from utilization of generics. [redacted]

140. **The Government Loses The Benefit Of Normal Price Competition.** The DEFENDANTS' false claims scheme has also deprived the Government of the benefits of normal price competition causing it in some cases to pay over one thousand percent above the price that would be set by normal market forces, but for the DEFENDANTS' false price and cost representations.

141. **Reported Prices On Drugs Sometimes Rose While Actual Prices Stayed Constant Or Decreased.** The Government and its health program beneficiaries are damaged when the DEFENDANTS create a financial inducement for Providers to order drugs by continually increasing the spread over time. [redacted]



142. The actions of the DEFENDANTS alleged herein result in grossly excessive amounts being paid to their customers by the Medicare and State Medicaid Programs for claims submitted for the specified drugs. The exorbitant payments induce physicians, clinics and pharmacies to increase utilization of the specified drugs The financial inducement was so great for many of the specified drugs that the profits derived from the provision of the specified drugs greatly exceeded the physicians' professional fees and provided what can only be characterized as "windfall profits." Over the last six (6) years, the Relator's business has all but been extinguished because of the Relator's refusal to benefit from the false and fraudulent claims schemes specified herein. The Relator has been unable to effectively compete with those physicians, clinics and pharmacies who benefit from the DEFENDANTS' false claims scheme because the financial inducement to the prescribing physicians often exceeds their compensation from the practice of medicine.

143. **The Dollar Amount Of The Financial Inducement To Providers From The False Price Scheme Can Be Enormous.** The financial inducement to those in a position to increase the utilization of the DEFENDANTS' drugs is illustrated by the examples of common drug therapies using certain of the specified drugs contained in Exhibit 5 hereto.

144. **Illegal Profit Spreads Are Often Enhanced By Additional Unlawful Financial Inducements Such As Free Goods, Direct Monetary Payments, Rebates,**

And Agreements To Falsify Invoices. The DEFENDANTS further act to increase the illegal profit spread, over and above that resulting from their false price and cost reports, through additional unlawful financial inducements which are concealed from the Government such as:

a) Providing or arranging for the delivery of free goods in exchange for the purchase of the DEFENDANTS' specified drugs, the value of which is concealed from the Government, resulting in an additional spread between the true acquisition cost of the specified drugs and the false prices upon which Medicare and Medicaid reimburse.

b) Making direct monetary payments to the Provider ordering the drugs and concealing the true purpose of the payment by classifying it as a "marketing grant", "educational grant", "administrative fee", "research grant" or other name when the payment is, in truth, a financial inducement for ordering the drugs.

c) Paying rebates to the Providers which are concealed from the Government.

d) Falsifying invoice prices to conceal additional reductions in the Provider's true acquisition cost of the drugs.

145. Each of the methods employed by the DEFENDANTS in paying illegal financial inducements has the effect of misleading the Medicare and Medicaid Programs about the Providers' cost of the drugs and of impeding the Programs' ability to estimate acquisition costs. The DEFENDANTS' actions result in claims being paid at exorbitant amounts.

SECTION NO. 9

THE DEFENDANT DRUG MANUFACTURERS' KNOWLEDGE OF THE FALSE CLAIMS SCHEME

146. The DEFENDANTS are prohibited by the False Claims Act from making false representations in connection with claims for Government funds, are required by the Food and Drug Act to report true prices and are prohibited by the Medicare and Medicaid Anti-Kickback laws from arranging financial inducements for Providers.

147. The patients and third party payers, including the Medicare and State Medicaid Programs, are not aware of the prices actually paid for the specified drugs by the physician, clinic or pharmacy presenting the claim for payment. The DEFENDANTS concealed from the Medicare and State Medicaid Programs price reductions occurring due to competition in the marketplace and falsely and fraudulently represented drug prices that far exceeded the truthful prices.

148. At all times material to this action, each of the DEFENDANTS acted "knowingly" as that term is defined at 31 U.S.C. §3729(b) by, among other things:

a) Causing the presentation of false and fraudulent claims for payment or approval by the Medicare and States Medicaid programs; and

b) Making and using false statements and/or records for the purpose of getting false or fraudulent claims approved or paid by the Medicare and State Medicaid Programs.

149. The DEFENDANT DRUG MANUFACTURERS knew or recklessly disregarded or acted in deliberate ignorance of the fact that their conduct would cause

Medicare/Medicaid to pay claims for the specified drugs in amounts exceeding that contemplated by applicable law, in part, because:

(a) Each of the DEFENDANT DRUG MANUFACTURERS knew or recklessly disregarded or acted in deliberate ignorance of the fact that Medicaid was required to pay claims based upon the drugs' Estimated Acquisition Cost ("EAC") to the Provider submitting the claim. 42 C.F.R. §447.331.

(b) Each of the DEFENDANT DRUG MANUFACTURERS knew or recklessly disregarded or acted in deliberate ignorance of the fact that federal statutes and regulations limited payment of Medicaid claims for the specified drugs to a reasonable estimation of the acquisition cost.

(c) Each of the DEFENDANTS knew or recklessly disregarded or acted in deliberate ignorance of the fact that federal statutes and regulations limit payment of Medicare Part B claims for the specified drugs to 80% of a reasonable cost, one that reflects the true cost of the drug. *See* 42 C.F.R. 405.517.

(d) Each of the DEFENDANT DRUG MANUFACTURERS knew or recklessly disregarded or acted in deliberate ignorance of the fact that neither Medicare nor Medicaid was authorized or permitted by applicable law to pay claims for the specified drugs in excessive amounts.

(e) Each DEFENDANT DRUG MANUFACTURER knew or recklessly disregarded or acted in deliberate ignorance of the fact that the State Medicaid Programs contracted through their fiscal agents with First Databank and Medi-Span to obtain the DEFENDANT's reported prices and costs and used the prices from First Databank and

Medi-Span to establish the estimated acquisition cost for the specified drugs for reimbursement purposes.

(f) Each DEFENDANT knew or recklessly disregarded or acted in deliberate ignorance of the fact that Medicare, through its Carriers and DMERCs, utilized DEFENDANTS' reported AWP prices as contained in Red Book, to establish its reimbursement amounts for the specified drugs.

(g) Each of the DEFENDANTS knew or recklessly disregarded or acted in deliberate ignorance of the fact that the State Medicaid Programs utilized DEFENDANT'S reported prices and costs to calculate the Estimated Acquisition Cost.

(h) Each of the DEFENDANT DRUG MANUFACTURERS knew or recklessly disregarded or acted in deliberate ignorance of the fact that they were supplying to First DataBank, Red Book and Medi-Span, prices and costs which these reporting compendia reported to Medicare and/or Medicaid and that these compendia relied solely on DEFENDANTS to obtain its prices.

(i) The DEFENDANTS knew or recklessly disregarded or acted in deliberate ignorance of the fact that they required wholesalers to report back to DEFENDANTS, and that wholesalers did in fact routinely report back to the DEFENDANTS, all prescription drug sales by NDC number, provider name and the actual price the Provider had paid.

(j) Each of the DEFENDANTS knew, and in fact, closely monitored the prices, with and without discounts, that Providers as well as wholesalers were paying for DEFENDANTS' specified drugs. Such information was of utmost importance to

DEFENDANTS in conducting their business affairs such as calculating and projecting revenue and profits, and making marketing, manufacturing and distribution decisions.

(k) Each of the DEFENDANTS had information readily available to them which would have enabled them to report price and cost information which fairly and reasonably represented sales in the marketplace.

(l) Each of the DEFENDANTS was, at a minimum, generally aware of the size of the "Spread" for their respective specified drugs under both Medicare and Medicaid.

(m) The DEFENDANTS knew or recklessly disregarded or acted in deliberate ignorance of the fact that the prices they reported to First DataBank, Red Book and Medi-Span were vastly higher than, and bore no relation whatsoever to, the actual prices which Providers were paying for their specified drugs.

(n) The DEFENDANTS knew or recklessly disregarded or acted in deliberate ignorance of the fact that, all other factors being equal, the greater the "Spread" on a drug, the greater the likelihood a Provider would purchase that drug versus a competing brand or generic drug.

(o) Each of the DEFENDANTS systematically concealed or otherwise failed to report decreases in the actual prices to the Providers of the specified drugs.

150. Each of the DEFENDANT DRUG MANUFACTURERS knew or recklessly disregarded or acted in deliberate ignorance of the fact that Federal and State statutes and regulations prohibited them from making misleading representations about the specified drugs, including misleading price or cost representations.

151. Each of the DEFENDANT DRUG MANUFACTURERS was required to comply with the Federal Food, Drug and Cosmetic Act 21 U.S.C. §321 et seq., and the regulations promulgated pursuant thereto.

152. The price and cost representations about the specified drugs constituted advertising that was included in the "labeling" provisions of the Federal Food and Drug Act and related regulations. 21 U.S.C. §§201(m); 202.1(k)(2).

153. Each of the DEFENDANT DRUG MANUFACTURERS is prohibited from disseminating any information about their prices or costs of the specified drugs that was "false or misleading in any particular . . ." 21 U.S.C. §§5.02; 302(b).

154. Each of the DEFENDANT DRUG MANUFACTURERS possessed a duty to assure that their representations about prices and costs of the specified drugs were not misleading, taking into account:

> " . . . not only representations made or suggested by statement, word, design, device, or any combination thereof, but also to the extent to which the labeling or advertising fails to reveal facts material in light of such representations"

21 U.S.C. §201(n).

155. The DEFENDANT DRUG MANUFACTURERS regularly made direct representations of false price and cost information to State Medicaid Programs that were utilized in approving and paying claims.

156. The DEFENDANT DRUG MANUFACTURERS were each fully capable of making truthful representations about prices and costs of the specified drugs and did so when it was economically beneficial to them, a fact which further indicates that they acted

with knowledge, as when the DEFENDANTS' supplied drug price reports to the federal government in connection with the Medicaid Rebate Program.

157. The DEFENDANT DRUG MANUFACTURERS each participated in the Medicaid Rebate Program (the "Rebate Program") mandated by the Federal Omnibus Budget Reconciliation Act of 1990 ("OBRA '90") and thus were required to pay rebates to State Medicaid Programs. The goal of the Rebate Program was to provide Medicaid with the benefit of the drug manufacturers' best prices. In calculating rebates it was in the economic interests of the DEFENDANT DRUG MANUFACTURERS to report the lowest Average Manufacturers Price ("AMPs") possible based upon the data available to them.

158. With respect to the drugs at issue in this case, when reporting prices for reimbursement purposes the DEFENDANT DRUG MANUFACTURERS falsely reported amounts far in excess of those reported for Rebate Program purposes. Therefore, when it benefitted the DEFENDANT DRUG MANUFACTURERS to report high prices in order to maximize the reimbursement amount for Providers, they used the false and grossly inflated prices and, when it benefitted the DEFENDANT DRUG MANUFACTURERS to report their true prices, which were much lower, to minimize the rebates they were required to pay the Rebate Program, they used the true prices.

159. The knowledge or gross recklessness of DEFENDANTS is further shown by the Rebate Program because the vast difference between the AMP's being reported for federal rebate purposes and prices and costs being reported for reimbursement purposes made it obvious that the reported reimbursement costs and prices were grossly inflated, yet they were never corrected.

160. Each DEFENDANT DRUG MANUFACTURER was on notice that it was prohibited by federal statute from paying, or causing the payment of, directly or indirectly, money or other financial benefit to induce its customers to order the specified drugs when the Medicare or State Medicaid Programs would be paying claims. 42 U.S.C. §1320a-7b(b)(2).

161. Notwithstanding the legislative intent of the Food Drug and Cosmetic Act, the DEFENDANTS, acting individually and in concert with one another, purposely created confusion and made false and misleading statements about drug pricing in order to deceive the United States Government and the States' Medicaid Programs. For several years, various Governmental agencies including the HHS Office of Inspector General "OIG" and the General Accounting Office "GAO" attempted to examine the issue of the reasonableness of reimbursements by the Medicare and States' Medicaid Programs for many of the drugs at issue in this Fourth Amended Complaint. The OIG's and GAO's efforts were thwarted, in part, by the DEFENDANTS withholding and concealing pertinent information that was being sought by the OIG and GAO. The OIG and GAO attempted through numerous published reports to identify the problem of unreasonable reimbursements; however, they were unsuccessful due to the actions of the DEFENDANTS. The DEFENDANTS concealed and disguised the unreasonable reimbursements from the United States Government and States' Medicaid Programs, in part, by the following facts and circumstances:

a) The DEFENDANTS can and do make truthful representations of price and costs for many of their drugs sold in retail community pharmacies and, in some

instances, infusion, [redacted] and inhalation drugs and [redacted] sold to physician groups, outpatient clinics and pharmacies.

b) Some of the DEFENDANTS make representations of cost and price in terms of "List Price," "Wholesale Net," Direct Price "DP" or "DIRP,"or Wholesaler Acquisition Costs, "WAC," to which Medical Economics and First DataBank apply an industry average mark-up and establish an AWP.

c) Some of the DEFENDANTS make representations of cost and price in terms of both AWP and DP (or DIRP).

d) All of the DEFENDANTS make or cause to be made falsely inflated price and cost representations of one or more of Wholesale Net Price/WAC, Direct Price and/or AWP that were utilized by the government in calculating and paying drug reimbursements.

162. Notwithstanding the DEFENDANTS' knowledge that the Government relied upon the DEFENDANTS' representations of price and cost and their knowledge of the applicable statutory requirements and prohibitions, each of the DEFENDANTS repeatedly, systematically and falsely reported inflated price and cost information, including but not limited to:

a) [redacted]

[redacted]

b) [redacted]

163. The grossly excessive profits have led to a proliferation of illegal split fee arrangements between the drug manufacturers' customers and persons or entities who are in a position to refer patients. The split fee/kickbacks also serve as a financial inducement for the referrals of more patients and greater utilization of the products.

164. In systematic and ongoing written and verbal communications with customers, the DEFENDANTS "marketed the spread" by encouraging and inducing customers to submit claims to Medicare and Medicaid to receive the excessive payments resulting from the DEFENDANTS' false price and cost representations.

SECTION NO. 10

THE DEFENDANTS HAVE REPEATEDLY UNDERMINED THE VARIOUS EFFORTS THAT FEDERAL AND STATE GOVERNMENTS HAVE MADE TO ENSURE THAT GOVERNMENT DRUG REIMBURSEMENT AMOUNTS ARE REASONABLE

165. The DEFENDANTS have each knowingly and actively impeded the numerous efforts made by Government to provide for reimbursement of prescription drugs at a reasonable rate.

166. **Defendants Intentionally Impede Governments' Efforts to Accurately Estimate Providers' Drug Costs under Medicare/Medicaid.** DEFENDANTS impede such efforts on the part of the Government by means of the knowing reporting of inflated price and cost information alleged throughout this Fourth Amended Complaint and by additional affirmative acts such as those alleged herein.

167. **Some State Medicaid Programs Have Gone To Exceptional Lengths In Their Efforts To Verify That Drug Manufacturers Provide Good Faith Price And Cost Information For Reimbursement Purposes.** By way of example, the Texas Medicaid authorities, during the time at issue in this Fourth Amended Complaint, required each of the DEFENDANTS to certify, in writing, their price and cost representations as a condition to their drugs being covered for reimbursement. The Relator's investigation has revealed that each of the DEFENDANTS, when responding to Texas, either affirmatively lied about their true prices, or omitted material information in order to mislead the Texas Medicaid officials.

168. Had the DEFENDANTS truthfully disclosed the price and cost information about the specified drugs, Texas Medicaid would have set reimbursement amounts for the specified drugs consistent with a reasonable estimation of acquisition cost. Because each of the DEFENDANTS having a duty to make truthful disclosures made false statements or omissions about the specified drugs, Texas Medicaid reimbursement has been paid at substantially greater amounts than intended by applicable law and Texas Medicaid policy.

169. **The DEFENDANTS Thwarted Governments' Efforts to Receive the Benefit of Drug Manufacturers' Best Prices under the Medicaid Rebate Program.** As previously alleged herein, the DEFENDANTS have each participated in the Rebate Program and as such were required to calculate their drugs BP and/or AMP.

170. If a manufacturer truthfully reports its AMP and WAC they should be very close to, if not the same, amount. However, for reimbursement purposes the DEFENDANTS have in many instances falsely and fraudulently represented inflated (or caused to be inflated) AWP's and WAC's that are in some cases more than 500% over their AMP's. These inflated reported prices and costs virtually nullify the intended effect of the Rebate Program which is to provide the Government with the benefit of the DEFENDANTS' best prices in the market place.

SECTION NO. 11

[redacted]

171. [redacted]

PAGES 78 THROUGH 109 HAVE BEEN

REDACTED,

WHICH INCLUDED THE CONTINUATION OF

SECTION 11 THROUGH SECTION 17

AND PARAGRAPHS 172 THROUGH 184.

SECTION NO. 18

THE SPECIFIC FALSE PRICE AND COST REPRESENTATIONS OF DEFENDANT DEY

185. Throughout the period starting from on or before December 31, 1994 and continuing through the present date, Defendant DEY knowingly caused Medicare/Medicaid to pay false or fraudulent claims for prescription drugs and/or biologicals (collectively referred to in this Section as the "drugs") including the drugs specified in this Section, and further made or used false or fraudulent records and/or statements to get such claims paid or approved. As a result of the said actions of Defendant DEY and those persons and entities acting directly or indirectly in concert with Defendant DEY, Medicare/Medicaid paid grossly excessive, unreasonable and unlawful amounts for claims for the drugs, including those specified in this Section. The acts committed by Defendant DEY that caused Medicare/Medicaid to pay or approve said false or fraudulent claims included, but were not necessarily limited to, knowingly making false or fraudulent representations about prices and costs of the drugs, including those specified in this Section, which Defendant DEY knew would be utilized by Medicare/Medicaid in paying or approving claims for such drugs and using the Spread as a financial inducement to increase sales of the Defendant's drugs. Each of said representations was in fact utilized by Medicare/Medicaid in paying or approving claims for the drugs, including those specified in this Section.

186. Defendant DEY knowingly caused its false or fraudulent price and cost representations to be published in the years specified in this Section in Red Book, Blue Book and First DataBank's Automated Services and Medi-Span and further made or used false records or statements regarding its prices and costs of the drugs, including those

specified in this Section and submitted same to the Medicare and States' Medicaid Programs continuously throughout the years specified in this Section. By way of example, the said false price and cost representations as they were reported by Defendant DEY and reflected in Red Book, Blue Book, First DataBank and the inflated Medicaid reimbursement amounts calculated by Florida and Texas have been organized into a chart form for certain of the drugs in question. Amounts contained in the Florida Medicaid reimbursement column reflect the falsely inflated reported First DataBank WAC costs because Florida's reimbursement methodology for the years listed in each chart was WAC (as reported in First DataBank) plus 7%. Amounts contained in the Texas WEAC (Wholesale Estimated Acquisition Cost) reimbursement column also reflect the fact that the Defendant's price and cost representations were falsely inflated as explained more fully in ¶ 110, herein. The amount listed under the Relator's Cost column reflects the actual prices that were available to the Relator for the listed drugs from DEY or a wholesaler. As a very small infusion pharmacy, the Relator did not always receive the lowest prices available to volume purchasers. Accordingly, in many instances the actual cost to Providers for the drug was significantly lower than that paid by the Relator. In instances where a Provider did pay less, the Spread on said drug would have been correspondingly greater than that received by the Relator. A listing of drugs with respect to which DEY knowingly caused Medicare/Medicaid to pay falsely inflated reimbursement amounts by reporting falsely inflated drug costs and prices is contained in Exhibit 6 attached hereto.

DEFENDANT DEY

**Albuterol Sulfate .083%
3 ml, 25s
NDC # 49502-0697-03
HCPCS J7620**

Year	False "AWP" Reported Through Red Book	False "AWP" Reported Through FDB Blue Book	False "AWP" Reported To CA Through FDB Automated System	False Direct Price Reported Through FDB Blue Book (1993-1996) And/Or Automated System (1997-2001)	Texas "WEAC" Medicaid Reimburse-ment Based On False Reported Prices	Florida Medicaid Reimbursement Based On False Reported "WAC"	Relator's Cost
1993	$32.30	$32.29		$26.50		$26.69	
1994	$30.25	$30.24	$30.24			$20.27	$8.50
1995	$30.25	$30.24	$30.24			$26.48	$8.50
1996	$30.25	$30.24	$30.24			$26.48	$7.75
1997	$30.25		$30.25		$16.24	$26.48	$7.75
1998	$30.25		$30.25			$26.48	$9.50
1999	$30.25						
2000	$30.25				$5.99		$4.69
2001	$30.25				$6.72		$4.10

**Acetylcysteine Solution 10%
4 ml, 12s
NDC # 49502-0181-04
HCPCS J7610**

Year	False "AWP" Reported Through Red Book	False "AWP" Reported Through FDB Blue Book	False "AWP" Reported To CA Through FDB Automated System	False Direct Price Reported Through FDB Blue Book (1993-1996) And/Or Automated System (1997-2001)	Texas "WEAC" Medicaid Reimburse-ment Based On False Reported Prices	Florida Medicaid Reimbursement Based On False Reported "WAC"	Relator's Cost
1993	$67.80	$67.80					
1994	$67.80	$67.80					$12.48
1995	$67.80	$67.80	$67.80		$28.90		$12.48
1996	$67.80	$67.80	$67.80		$28.90	$27.60	$12.48
1997	$67.80		$67.80		$28.90		$12.48
1998	$67.80		$67.80		$28.90		$12.48
1999	$67.80				$28.90		
2000	$67.80				$22.40		$11.98

DEFENDANT DEY							
2001	$67.80				$22.40		$14.26
Acetycysteine Solution 20% 4 ml, 12s NDC # 49502-0182-04 HCPCS J7615							
Year	**False "AWP" Reported Through Red Book**	**False "AWP" Reported Through FDB Blue Book**	**False "AWP" Reported To CA Through FDB Automated System**	**False Direct Price Reported Through FDB Blue Book (1993-1996) And/Or Automated System (1997-2001)**	**Texas "WEAC" Medicaid Reimburse-ment Based On False Reported Prices**	**Florida Medicaid Reimbursement Based On False Reported "WAC"**	**Relator's Cost**
1993	$81.36	$81.36		$34.20		$33.25	
1994	$81.36	$81.36				$33.25	$12.60
1995	$81.36	$81.36				$33.25	$12.60
1996	$81.36	$81.36				$33.25	$12.60
1997	$81.36		$81.36			$33.25	$12.60
1998	$81.36					$33.25	$12.60
1999	$81.36						
2000	$81.36						$13.31
2001	$66.00						$17.36
Cromolym Sodium USP 20 mg/2ml 60s NDC # 49502-0689-02 HCPCS J7630							
Year	**False "AWP" Reported Through Red Book**	**False "AWP" Reported Through FDB Blue Book**	**False "AWP" Reported To CA Through FDB Automated System**	**False Direct Price Reported Through FDB Blue Book (1994-1996) And/Or Automated System (1997-2001)**	**Texas "WEAC" Medicaid Reimburse-ment Based On False Reported Prices**	**Florida Medicaid Reimbursement Based On False Reported "WAC"**	**Relator's Cost**
1994		$42.00	$42.00			$36.59	$24.50
1995	$42.00	$42.00	$42.00			$36.59	$24.50
1996	$42.00	$42.00	$42.00			$36.59	$18.15
1997	$42.00	$42.00	$42.00		$38.30	$36.59	$18.15
1998	$42.00	$42.00	$42.00			$36.59	$18.15
1999	$42.00						
2000	$42.00						$17.04
2001	$42.00						$9.91

DEFENDANT DEY

Metaproterenol Sulfate 0.4%
2.5 ml 25s
NDC # 49502-0678-03
HCPCS J7670

Year	False "AWP" Reported Through Red Book	False "AWP" Reported Through FDB Blue Book	False "AWP" Reported To CA Through FDB Automated System	False Direct Price Reported Through FDB Blue Book (1993-1996) And/Or Automated System (1997-2001)	Texas "WEAC" Medicaid Reimburse-ment Based On False Reported Prices	Florida Medicaid Reimbursement Based On False Reported "WAC"	Relator's Cost
1993	$30.75	$30.75		$15.39		$14.69	
1994	$30.75	$30.75	$30.75			$14.69	$6.25
1995	$30.75	$30.75	$30.75			$14.69	$6.25
1996	$30.75	$30.75	$30.75			$11.77	$6.25
1997	$30.75		$30.75		$12.32	$11.77	$6.25
1998	$30.75		$30.75			$11.77	$6.25
1999	$30.75						
2000	$30.75				$ 7.84		$6.66
2001	$30.75				$ 9.97		$7.20

Metaproterenol Sulfate 0.6%
2.5 ml 25s
NDC # 49502-0678-03
HCPCS J7672

Year	False "AWP" Reported Through Red Book	False "AWP" Reported Through FDB Blue Book	False "AWP" Reported To CA Through FDB Automated System	False Direct Price Reported Through FDB Blue Book (1993-1996) And/Or Automated System (1997-2001)	Texas "WEAC" Medicaid Reimburse-ment Based On False Reported Prices	Florida Medicaid Reimbursement Based On False Reported "WAC"	Relator's Cost
1993	$30.75	$30.75		$15.39			
1994	$30.75	$30.75	$30.75				$6.25
1995	$30.75	$30.75	$30.75				$6.25
1996	$30.75	$30.75	$30.75		$12.32	$11.77	$6.25
1997	$30.75		$30.75		$12.32		$6.25
1998	$30.75		$30.75		$12.32		$6.25
1999	$30.75				$12.32		
2000	$30.75				$ 9.97		$6.66

DEFENDANT DEY							
2001	$30.75				$ 9.97		$7.20

As a direct and proximate result of the actions of the Defendant DEY alleged herein, the United States has sustained damages recoverable under the False Claims Act, together with triple damages, penalties, attorneys' fees and costs.

SECTION NO. 19

[redacted]

187. [redacted]

PAGES 116 THROUGH 160 HAVE BEEN

REDACTED,

WHICH INCLUDED CONTINUATION OF

SECTION 19 THROUGH SECTION 33

AND PARAGRAPHS 188 THROUGH 217.

[redacted]

COUNT I

FALSE CLAIMS ACT;
CAUSING PRESENTATION OF FALSE OR FRAUDULENT CLAIMS

218. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-CARE, on behalf of the UNITED STATES and on behalf of the Relator, against the Defendants: [redacted] DEY INC. [redacted] EMD PHARAMCEUTICALS, INC. [redacted] LIPHA, S.A.; [redacted]; MERCK KGaA; MERCK-LIPHA S.A. [redacted]

[redacted], under the False Claims Act, 31 U.S.C. §§3729-3732.

219. Relator realleges and incorporates by reference paragraphs 1 through 217 as if fully set forth herein and further alleges as follows:

220. The DEFENDANTS, from the dates specified in Sections 11 through 33, to the present date [redacted] knowingly [as defined in 31 USC, §3729(b)] caused to be presented to officers or employees of the UNITED STATES GOVERNMENT and STATE GOVERNMENTS false or fraudulent claims for payment or approval, in that the DEFENDANTS caused to be presented to officers or employees of the UNITED STATES GOVERNMENT and STATE GOVERNMENTS false or fraudulent price and cost information for the specified drugs (as the term "specified drugs" has been defined throughout the Complaint) and caused the UNITED STATES and STATE GOVERNMENTS to pay out sums of money to the Providers and suppliers of the DEFENDANTS' specified drugs, grossly in excess of the amounts permitted by law, resulting in great financial loss to the UNITED STATES and STATE GOVERNMENTS.

221. Because of the DEFENDANT PHARMACEUTICAL MANUFACTURERS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of One Billion Dollars ($1,000,000,000.00), all in violation of 31 U.S.C. §3729(a)(1)

COUNT II

FALSE CLAIMS ACT; CAUSING A FALSE RECORD OR STATEMENT TO BE MADE OR USED TO GET A FALSE OR FRAUDULENT CLAIM PAID OR APPROVED BY THE GOVERNMENT

222. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-CARE, on behalf of the UNITED STATES and on behalf of the Relator, against the Defendants:

[redacted]

DEY INC.[redacted] EMD PHARAMCEUTICALS, INC.[redacted]

[redacted] LIPHA, S.A.[redacted] MERCK KGaA;

MERCK-LIPHA S.A.[redacted]

[redacted] under the False Claims Act, 31 U.S.C. §§3729-3732.

223. Relator realleges and incorporates by reference paragraphs 1 through 217 as if fully set forth herein and further alleges as follows:

224. The DEFENDANTS, from the dates specified in Sections 11 through 33, to the present date [redacted] knowingly [as defined in §3729(b)] caused false records or statements to be made or used to get false or fraudulent claims to be paid or approved by the GOVERNMENT, in that the DEFENDANTS, caused false records or statements of prices and costs of the DEFENDANTS' drugs specified herein to be used by the GOVERNMENT to pay or approve claims presented by the Providers and suppliers of the DEFENDANTS' specified drugs, which claims were grossly

in excess of the amounts permitted by law, resulting in great financial loss to the UNITED STATES and STATE GOVERNMENTS.

225. Because of the DEFENDANTS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of One Billion Dollars ($1,000,000,000.00), all in violation of 31 U.S.C. §3729(a)(2).

COUNT III

FALSE CLAIMS ACT; CAUSING FALSE RECORDS OR STATEMENTS TO BE USED TO CONCEAL AN OBLIGATION TO PAY MONEY TO THE GOVERNMENT

226. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-CARE, on behalf of the UNITED STATES and on behalf of the Relator, against the Defendants:

[redacted] DEY INC. [redacted] EMD PHARAMCEUTICALS, INC.; [redacted] LIPHA, S.A. [redacted] MERCK KGaA; MERCK-LIPHA S.A. [redacted]

[redacted], under the False Claims Act, 31 U.S.C. §§3729-3732.

227. Relator realleges and incorporates by reference paragraphs 1 through 217 as if fully set forth herein and further alleges as follows:

228. The DEFENDANTS, from on or before the dates specified in Sections 11 through 33, to the present date [redacted] knowingly [as defined in §3729(b)] caused false records or statements to be made or used to conceal obligations to pay money to the GOVERNMENT, in that: the DEFENDANTS knew that the UNITED STATES' Medicare Program and the States' Medicaid Programs had used the DEFENDANTS' false price and cost representations for purposes of paying or approving claims of the Providers and suppliers of the DEFENDANTS' specified drugs; the DEFENDANTS knew that sums of money paid by the UNITED STATES and States' Governments to the Providers and suppliers of the DEFENDANTS' specified drugs were grossly in excess of the amounts permitted by law; the DEFENDANTS knew it was the obligation of the UNITED STATES Medicare Part B carriers and State Governments to recoup governments' funds paid in excess of the amounts permitted by law; the DEFENDANTS, nevertheless, continued to conceal the fact that they had caused to be made or used false records or statements of prices and costs for the specified drugs that were grossly in excess of the reasonable amounts permitted by law and to conceal from the GOVERNMENT an obligation to pay to the GOVERNMENT the excessive reimbursement amounts paid to Providers for which DEFENDANTS were directly responsible.

229. Because of the DEFENDANTS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of One Billion Dollars ($1,000,000,000.00), all in violation of 31 U.S.C. §3729(a)(7).

COUNT IV

FALSE CLAIMS ACT; CAUSING PRESENTATION OF FALSE OR FRAUDULENT CLAIMS; ILLEGAL REMUNERATION

230. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-CARE, on behalf of the UNITED STATES and on behalf of the Relator, against the Defendants: [redacted] DEY INC. [redacted] EMD PHARAMCEUTICALS, INC. [redacted] LIPHA, S.A. [redacted] MERCK KGaA; MERCK-LIPHA S.A. [redacted], under the False Claims Act, 31 U.S.C. §§3729-3732.

231. Relator realleges and incorporates by reference paragraphs 1 through 217 as if fully set forth herein and further alleges as follows:

232. The DEFENDANTS, from the dates specified in Sections 11 through 33, to the present date [redacted] knew

that the prices charged to their customers for the specified drugs were significantly reduced in amount from the prices and costs represented by the DEFENDANTS and upon which the DEFENDANTS knew Medicare and Medicaid claims would be approved and paid. Accordingly, the DEFENDANTS have each knowingly offered or paid, or caused to be offered or paid, directly or indirectly, overtly or covertly, in cash or in kind, remuneration to their customers in the form of price reductions and/or in the form of illegal remuneration from the Medicare and/or States' Medicaid Programs to induce them to purchase, order or arrange or to recommend purchasing, arranging or ordering the specified drugs for which the DEFENDANTS knew that payment would be made, in whole or in part, by the Medicare and States' Medicaid Programs. Such financial inducement is specifically prohibited by 42 U.S.C. §1320a-7b(b) and 18 U.S.C §2.

233. The DEFENDANTS' knowing and willful actions in arranging for their customers to receive remuneration prohibited by 42 U.S.C. §1320a-7b(b), in causing the omission of material information from the claims, and in causing the failure to properly disclose and appropriately reflect the remuneration in the claims, caused the claims for the specified drugs to be false and fraudulent claims and caused the claims to be presented to the Medicare and States' Medicaid Programs for payment and approval in violation of 31 U.S.C §3729(a)(1).

234. Because of the DEFENDANTS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of One Billion Dollars ($1,000,000,000.00) all in violation of 31 U.S.C. §3729(a)(1).

COUNT V

FALSE CLAIMS ACT; CAUSING A FALSE RECORD OR STATEMENT TO BE MADE OR USED TO GET A FALSE OR FRAUDULENT CLAIM PAID OR APPROVED BY THE GOVERNMENT; PROHIBITED REFERRALS, CLAIMS AND COMPENSATION ARRANGEMENTS

235. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-CARE, on behalf of the UNITED STATES and on behalf of the Relator, against the Defendants: [redacted] DEY INC. [redacted] EMD PHARAMCEUTICALS, INC. [redacted] LIPHA, S.A. [redacted] MERCK KGaA; MERCK-LIPHA, S.A. [redacted], under the False Claims Act, 31 U.S.C. §§3729-3732.

236. Relator realleges and incorporates by reference paragraphs 1 through 217 as if fully set forth herein and further alleges as follows:

237. The DEFENDANTS, from the dates specified in Sections 11 through 33 to the present date [redacted] knowingly presented or caused to be presented, prohibited claims or bills to individuals and other entities for designated health services [outpatient prescription drugs] furnished pursuant to prohibited referrals from physicians, physician groups and/or outpatient clinics with which the DEFENDANTS had financial relationships, for which the DEFENDANTS knew that payment would be made, in whole or in part, by the Medicare and/or States' Medicaid Programs. Such prohibited referrals, claims, bills and compensation arrangements are specifically prohibited by 42 U.S.C. §1395nn(a)(1)(B) and 18 U.S.C §2.

238. The DEFENDANTS knowingly made or used or caused their referring physicians, physician groups or outpatient clinics to make or use false records or statements to get false or fraudulent claims and bills for the DEFENDANTS' outpatient prescription drugs to be paid or approved by the Medicare and/or States' Medicaid Programs.

239. The DEFENDANTS' knowing presentment or causing others to present, claims or bills to the Medicare and/or States' Medicaid Programs in violation of 42 U.S.C. §1395nn(a)(1)(B) without disclosing facts revealing said violations constituted the making or using, or the causing others to make or use, false records or statements to get a false or fraudulent claims paid or approved by the GOVERNMENT in violation of 31 U.S.C. §3729(a)(2).

240. Because of the DEFENDANTS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of One Billion Dollars ($1,000,000,000.00) all in violation of 31 U.S.C. §3729(a)(2).

COUNT VI

FALSE CLAIMS ACT; CONSPIRING TO DEFRAUD THE GOVERNMENT BY GETTING A FALSE OR FRAUDULENT CLAIM ALLOWED OR PAID

241. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-CARE, on behalf of the UNITED STATES and on behalf of the Relator, against the Defendants: [redacted] DEY INC. [redacted] EMD PHARMACEUTICALS, INC. [redacted] LIPHA, S.A. [redacted]; MERCK KGaA; MERCK-LIPHA, S.A. [redacted], under the False Claims Act, 31 U.S.C. §§3729-3732.

242. Relator realleges and incorporates by reference paragraphs 1 through 217 as if fully set forth herein and further alleges as follows.

243. This Count pertains to all DEFENDANTS manufacturing specified drugs which were multiple-source drugs subject to the "J Code" Medicare reimbursement methodology described

herein (for purposes of this Count each such drug is hereinafter referred to as "a J Code drug"). Each DEFENDANT which reported a falsely inflated AWP for a J Code drug is jointly and severally liable along with all other DEFENDANTS who reported a falsely inflated AWP for a J Code drug falling under the same HCPCS code for the sum of all falsely inflated reimbursement amounts under said HCPCS code in that they conspired to defraud the Government by getting a false claim paid or approved by Medicare via the submission of false or fraudulent price information for the inflated J Code drugs, which jointly caused the UNITED STATES to pay out sums of money to the Providers of the DEFENDANTS' J Code drugs which were grossly in excess of the amounts permitted by law, resulting in great financial loss to the UNITED STATES.

244. With respect to State Medicaid Programs, this Count also applies to all DEFENDANTS manufacturing specified drugs which: 1) were multiple-source drugs, 2) were subject to a State Medicaid reimbursement methodology similar to the Medicare "J Code" methodology described herein, and 3) had a falsely inflated reported AWP or another falsely inflated reported price or cost if such price or cost was utilized in creating an array of prices or costs from which one was selected for reimbursement of all versions of a given drug.

245. Each DEFENDANT'S liability as to this Count extends from the time it first reported a falsely inflated AWP, or in the case of Medicaid, a falsely inflated AWP or such other price or cost used to create the array of drug prices or costs, until such time, if any, each DEFENDANT stopped reporting said inflated AWP or, in the case of Medicaid, stopped reporting said inflated AWP or such other reported price or cost used to create the array of drug prices or costs from which one was selected for reimbursement purposes.

246. Because of the DEFENDANTS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of One Million Dollars ($1,000,000), all in violation of 31 U.S.C. §3729(a)(3).

REQUESTS FOR RELIEF

WHEREFORE, the Relator, on behalf of the UNITED STATES, demands that judgment be entered in its favor and against Defendants: [redacted] DEY INC. [redacted] EMD PHARAMCEUTICALS, INC [redacted] LIPHA, S.A. [redacted] MERCK KGaA; MERCK-LIPHA S.A. [redacted] with judgment to be entered against each DEFENDANT for the amount of damages: (1) to the States' Medicaid Programs arising (a) from claims for each DEFENDANT'S respective specified drugs and (b) jointly and severally with such other Defendants for damages as set forth in paragraphs 121 and paragraphs 241-246 herein;

and (2) to the Medicare Program arising from claims for those drugs classified under the HCPCS codes covering their specified drugs, and jointly and severally with such other Defendants whose drugs fall under said HCPCS codes, as follows:

1. On Count I (False Claims Act; Causing Presentation of False Claims) for triple the amount of the UNITED STATES' damages, plus civil penalties of no more than TEN THOUSAND DOLLARS ($10,000.00) and no less than FIVE THOUSAND DOLLARS ($5,000.00) for each false claim;

2. On Count II (False Claims Act; Causing False Statements To Be Used To Get False Claims Paid Or Approved By The GOVERNMENT) for triple the amount of UNITED STATES' damages plus civil penalties of no more than TEN THOUSAND DOLLARS ($10,000.00) and no less than FIVE THOUSAND DOLLARS ($5,000.00) for each false statement;

3. On Count III (False Claims Act; Causing False Statements To Be Used To Conceal An Obligation To Pay Money To The GOVERNMENT) for triple the amount of the UNITED STATES' damages plus civil penalties of no more than TEN THOUSAND DOLLARS ($10,000.00) and no less than FIVE THOUSAND DOLLARS ($5,000.00) for each false or fraudulent claim paid;

4. On Count IV (False Claims Act; Causing Presentation of False and Fraudulent Claims; Illegal Remuneration) for triple the amount of the UNITED STATES' damages, plus civil penalties of no more than TEN THOUSAND DOLLARS ($10,000.00) and no less than FIVE THOUSAND DOLLARS ($5,000.00) for each false claim;

5. On Count V (False Claims Act; Causing a False Record or Statement to be Made or Used to get a False or Fraudulent Claim Paid or Approved by the Government; Prohibited Referrals, Claims and Compensation Arrangements) for triple the amount of the UNITED

STATES' damages, plus civil penalties of no more than TEN THOUSAND DOLLARS ($10,000.00) and no less than FIVE THOUSAND DOLLARS ($5,000.00) for each false statement;

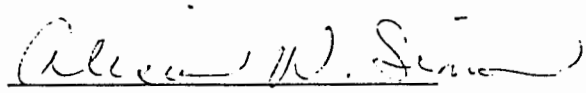
6. On Count VI (False Claims Act; Conspiring To Defraud The Government By Getting A False Or Fraudulent Claim Allowed Or Paid) for triple the amount of the UNITED STATES' and States' damages, plus civil penalties of no more than TEN THOUSAND DOLLARS ($10,000.00) and no less than FIVE THOUSAND DOLLARS ($5,000.00) for each false record or statement.

Further, the Relator, on its behalf, requests that it receive the maximum amount as permitted by law, of the proceeds of this action or settlement of this action collected by the UNITED STATES, plus an amount for reasonable expenses incurred, plus reasonable attorneys' fees and costs of this action. The Relator requests that its award be based upon the total value recovered, both tangible and intangible, including any amounts received from individuals or entities not parties to this action.

DEMAND FOR JURY TRIAL

A jury trial is demanded in this case.

Respectfully submitted,



James J. Breen
Florida Bar No. 297178
Alison Simon
Florida Bar No. 0109568
THE BREEN LAW FIRM, P.A.
P. O. Box 297470
Pembroke Pines, FL 33029
Telephone: 954-499-1171
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Sherrie R. Savett
Gary L. Azorsky
Susan S. Thomas
Jeanne A. Markey
Joy Clairmont
BERGER & MONTAGUE, P.C.
1622 Locust Street
Philadelphia, PA 19103
Telephone: 215-875-3000
Facsimile: 215-875-4636

Civil Action No: 95-1354-CIV-GOLD

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 11th day of December, 2002, I caused an original and a copy of this Fourth Amended Complaint to be filed under seal and in camera for sixty (60) days and not to be served on the Defendants named herein or until further order of this Honorable Court.

I HEREBY CERTIFY that prior to this 11th day of December, 2002, I caused a copy of this Fourth Amended Complaint and written supplemental disclosure letter of the Relator, VEN-A-CARE, to be served on the Government pursuant to Rule 4(i), Fed.R.Civ.P., prior to the filing of this Fourth Amended Complaint by: hand delivering a copy of the Fourth Amended Complaint and written supplemental disclosure letter of the Relator to the United States Attorney for the Southern District of Florida and Mark Lavine, Assistant United States Attorney, Southern District of Florida; and sending a copy of the Fourth Amended Complaint and written supplemental disclosure letter of the Relator by Certified Mail, Return Receipt Requested, to the Attorney General of the United States in Washington, D.C and T. Reed Stephens, Trial Attorney, Department of Justice.

Respectfully submitted,

James J. Breen
Florida Bar No. 297178
Alison W. Simon
Florida Bar No. 0109568
THE BREEN LAW FIRM, P.A.
P.O. Box 297470
Pembroke, Pines, FL 33029
Telephone: 954-499-1171
Facsimile: 954-499-1173

EXHIBIT "1"

: WBB

AT: 13055778545

TDH
TEXAS DEPARTMENT OF HEALTH

Texas Department of Health

William R. Archer III, M.D.
Commissioner of Health

http://www.tdh.state.tx.us

1100 West 49th Street
Austin, Texas 78756-3199
(512) 458-7111

Patti J. Patterson, M.D., M.P.H.
Executive Deputy Commissioner

Under the Omnibus Budget Reconciliation Act (OBRA) of 1990, the state of Texas Vendor Drug Program will continue to request completed questionnaire as a requirement for the production addition to the Texas Vendor Drug Index (TVDI). A form is included so that all necessary information from the manufacturer will be available for pricing and dosing recommendations. Questionnaires should be limited to no more than 20 per submittal request for any one month period. A separate questionnaire is to be submitted for each drug and strength. Please supply a cover sheet listing all products, strengths and package sizes for which you are submitting applications. Questions must be answered in full (NO - N/A). This form may be reproduced.

All inquiries regarding this questionnaire for BVD and revisions are to be directed to:

Texas Department of Health
Bureau Vendor Drug
1100 West 49th Street.
Austin, Texas 78756-3174

Drugs are listed in the BVD using the NDC number of the manufacturer or distributor who is holding the drug forth as his own and has his company's name on the label of the container that is sold to the pharmacy. If your company has a product to which the "New Drug Coverage" applies, please add the FDA approval date of the New Drug Application (NDA), Product License Approval (PLA), Establishment License Approval (ELA), or Antibiotic Drug Approval (ADA) to the questionnaire.

Martha McNeill, R.Ph.
Director of Product Management
Bureau of Vendor Drug
(512)338-6965
(512)338-6462-Fax
(512)338-6932-Secretary

EXHIBIT "1"

REQUEST FOR INFORMATION FOR NEW DRUG PRODUCT OR FOR ADDITIONAL INFORMATION OF PRODUCTS CURRENTLY INCLUDED IN TEXAS MEDICAID

Please fill out the following information for consideration on Texas Medicaid

LUDE A COPY OF FILE CARD, PACKAGE INSERT AND OR MATERIAL FOR PHYSICIANS

DRUG DESCRIPTION

)C. NO: ıltiple package size of same strength	PACKAGE QTY: products may be included)	
ODUCT BRAND NAME: NERIC NAME: STRUCTURALLY RELATED DRUGS:		
UG STRENGTH:		
)LOR:	FLAVOR:	ORANGE BOOK RATING:
)SAGE FORM:	IS THIS DRUG LEGEND OR OTC?	DEA SCHEDULE OF THE DRUG:
AXIMUM DAILY DOSE:		
COMMENDED DAILY DOSE:		
GREDIENTS/DESCRIPTION:		
LIST SHELF LIFE:		
ESTIMATED AVG. DURATION OF THERAPY:		
MAXIMUM DURATION OF TREATMENT:		

A - Drug products that FDA considers to be therapeutically equivalent to other pharmaceutically equivalent products.

B - Drug products that FDA at this time, considers not to be therapeutically equivalent to other pharmaceutically equivalent products.

C - Not listed in Orange Book

** NEW ADDITIONAL INFORMATION - revised (April 1, 1998)

TTACH COPIES OF PRICE LIST & ADD TO MAILING LIST IF NOT CURRENTLY LISTED**

PRICE INFORMATION

ERAGE OF SUGGESTED WHOLESALE PRICE TO PHARMACY (AWP)	$
CE TO WHOLESALER AND/OR DISTRIBUTOR	$
ECT PRICE TO PHARMACY	$
CE TO CHAIN WAREHOUSE	$
NSTITUTIONAL OR OTHER CONTRACT PRICE** ursing Home, Home Health Care)	$
HER PRICE	$

set of price lists is sufficient for multiple submittals.

otes: If prices vary by specific contract or customer arrangement, you may provide a price range.**

lease circle the companies to whom you report pricing information.

ST DATA BANK PRICE ALERT RED BOOK

DI-SPAN BLUE BOOK

TER:_____

Do you sell to distributors, repackagers, or relablers, other than full-service drug wholesalers, who in turn ell your product to the retail trade bearing your NDC number?

f yes, attach a listing.

Attach a copy of your sales agreement with retail pharmacists (contract, policy, etc)

Attach a copy of your Vendor Liability Insurance:

a. Included or

b. Previously submitted or unchanged. (Do not need to resubmit)

Available date through WHOLESALERS_____

ne of firm:			
dress:			
y:		State:	Zip:
ne and address of Manufacturer of drug:			
y:		State:	Zip:
ne and Address of representatives/government affairs persons covering the Texas area; if applicable:			
y:		State:	Zip:
one:			

s this product now marketed under an approved NDA or ANDA?

Submit a copy of the FDA letter of approval of the NDA or ANDA, or, if not applicable, a copy of the FDA letter of approval for marketing.

Please circle DESI classification of this product.

Non-DESI/IRS: safe and effective

DESI/IRS under review

LTE DESI/IRS for some indications

Non-Covered - LTE DESI/IRS for all indications

Non-Covered - LTE DESI/IRS withdrawn form the market

oduct added to the Texas Vendor Drug Program must bear the labeler code, as defined by the FDA, of the , with the exception of a bonafide full-service drug wholesaler, marketing the final sale to the provider.

ufacturers or distributors having one or more of their pharmaceuticals included in the program are responsible ubmitting notification of any changes pertaining to any of the above information not later than such revisions heduled to occur to:

Texas Department of Health
Bureau of Vendor Drug
Attn: Martha McNeill, R.Ph.
Director of Product Management
1100 West 49th Street
Austin, Texas 78756-3174

ify that the information submitted is correct to the best of my knowledge and that this product is not now in tion of either Federal or State Law. I also agree to inform the Texas Department of Health, in writing, of any ges in formulation, product status, price or availability as herein describe, within fifteen (15) days of such ge.

onsible Person (Type or Print) _____ Signature

ress _____ City _____ State _____ Zip

pany Name _____ ( ) _____ Telephone

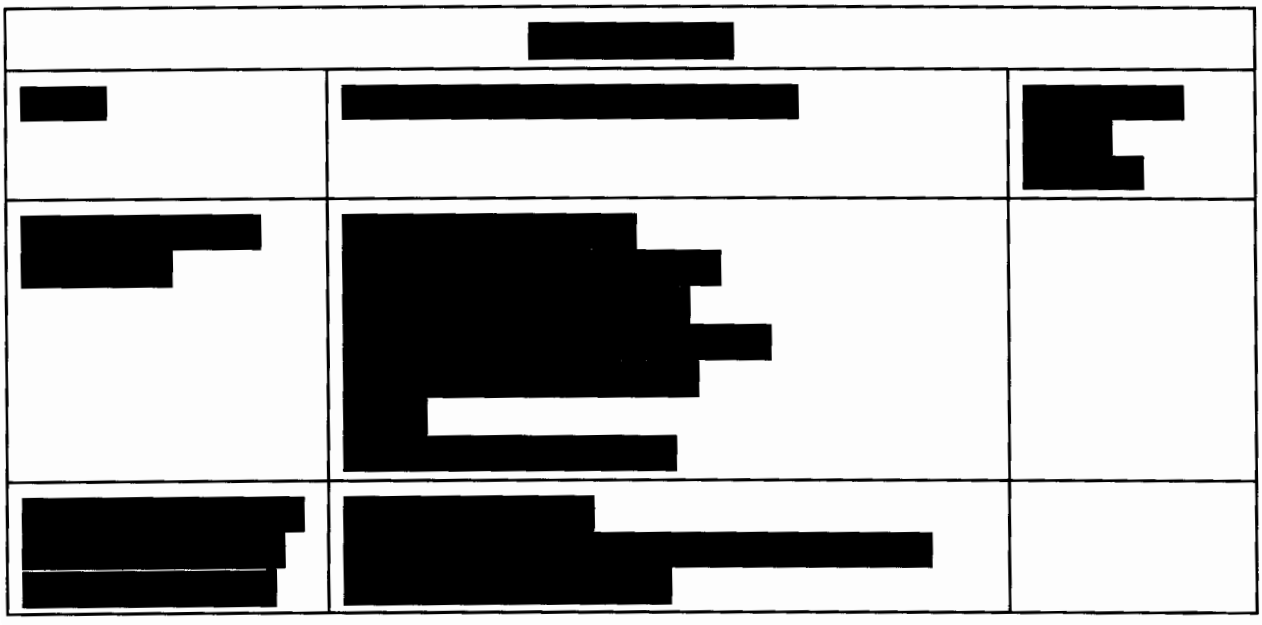
EXHIBIT "2"

EXHIBIT 2

PAGES 1 THROUGH 10 OF EXHIBIT 2 HAVE BEEN REDACTED

EXHIBIT 2
Page 11

DEY		
DRUG	**FDA APPROVED INDICATIONS**	**THE FALSE PRICE SPREAD**
Acetylcystine (Mucolytic)	Acute Bronchopulmonary Disease Pulmonary complications of Cystic Fibrosis Tracheostomy care	462%
Albuterol Sulfate (Broncodilator)	Relief & prevention of Bronchospasm in patients with Reversible Obstructive Airway Disease. Prevention of exercised-induced Bronchospasm	293%
Cromlyin Sodium (Antiasthma, Antiallergy)	Severe Bronchial Asthma Prevention of exercised-induced Bronchospasm	71%
Metapoterenol (Bronchodilator)	Bronchial Asthma Reversible Bronchospasm Acute Asthmatic attacks in children _ 6 years	392%
Sodium Chloride (Fluid)	To dilute Bronchodilator solutions for inhalation	85%



PAGES 12 THROUGH 22 OF EXHIBIT 2 HAVE BEEN REDACTED

EXHIBIT "3"

Case No: 95-1354-CIV-MARCUS

EXHIBIT 3
DRUGS WHERE THE MEDICARE PROGRAM'S 20% CO-PAYMENT EXCEEDS THE TOTAL PRICE OF THE DRUG
Page 1

Drug	HCPCS Code	1996 Florida Medicare Allowable	20% Co-Payment	1996 Relator's Cost
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Acetylcysteine 20% per ml	J7615	$ 1.37	$ 0.27	$ 0.26
Metaproterenol Sulfate 0.4%	J7670	$ 1.23	$ 0.25	$ 0.10
Metaproterenol Sulfate 0.6%	J7672	$ 1.23	$ 0 .25	$ 0.10

Case No: 95-1354-CIV-MARCUS

EXHIBIT 3
DRUGS WHERE THE MEDICARE PROGRAM'S
20% CO-PAYMENT
EXCEEDS THE TOTAL PRICE OF THE DRUG
Page 2

Drug	HCPCS Code	1996 Florida Medicare Allowable	20% Co-Payment	1996 Relator's Cost
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

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EXHIBIT “4"

EXHIBIT 4

**THE MEDICARE AND MEDICAID PROGRAMS
DUPED INTO PAYING AS MUCH OR MORE
FOR GENERIC DRUGS THAN THEIR EQUIVALENT BRAND**

EXHIBIT 4 HAS BEEN COMPLETELY REDACTED

PAGES 1 THROUGH 4

EXHIBIT "5"

EXHIBIT 5
EXAMPLES OF THE FINANCIAL INDUCEMENTS ARISING FROM COMMON DRUG THERAPIES USING CERTAIN SPECIFIED DRUGS

EXHIBIT 5

HAS BEEN COMPLETELY

REDACTED

PAGES 1 THROUGH 9

EXHIBIT "6"

EXHIBIT 6
ALL MIAMI PRICE FRAUD DRUGS

PAGES 1 THROUGH 104

OF EXHIBIT 6

HAVE BEEN REDACTED

EXHIBIT 6
ALL MIAMI PRICE FRAUD DRUGS
Page 105

Defendant	Drug	NDC #
Dey	Acetycysteine Solution 20% 4 ml, 12s	49502-0182-04
Dey	Acetylcysteine Solution 10% 10 ml, 3s	49502-0181-10
Dey	Acetylcysteine 10% 30 ml	49502-0181-30
Dey	Acetylcysteine 20% 10 ml	49502-0182-10
Dey	Acetylcysteine 20% 100 ml	49502-0182-00
Dey	Acetylcysteine Solution 10% 4 ml, 12s	49502-0181-04
Dey	Acetylcysteine 20% 30 ml	49502-0182-30
Dey	Albuterol Inhalation Solution 0.5%, 20 ml	49502-0196-20
Dey	Albuterol Sulfate 0.083% 3 ml, 30s	49502-0697-33
Dey	Albuterol Sulfate 0.083% 3 ml 60s	49502-0697-60
Dey	Albuterol Sulfate 0.083% 3 ml, 25s	49502-0697-03
Dey	Cromolyn Sodium 2 ml 60s	49502-0689-02
Dey	Cromolyn Sodium 2 ml 120s	49502-0689-12
Dey	Metaproterenol 0.4%	49502-0678-03
Dey	Metaproterenol 0.6% 2.5 ml 25 s	49502-0676-03

EXHIBIT 6
ALL MIAMI PRICE FRAUD DRUGS
Page 106

Defendant	Drug	NDC #
Dey	Sodium Chloride 0.9% 15 ml	49502-0830-15
Dey	Sodium Chloride 3% 15 ml 50s	49502-0640-15
Dey	Sodium Chloride 10% 15 ml 50s	49502-0641-15
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

EXHIBIT 6
ALL MIAMI PRICE FRAUD DRUGS
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HAVE BEEN REDACTED

C:\Documents and Settings\Jim Breen\My Documents\FEDERAL\ALLComplaints\FED-4th-amd-comp-redacted-dey-exh6.wpd